California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Legislation and Regulation Committee Report
October 15, 2003

Andrea Zinder, Chair
Dave Fong, Member

FOR ACTION

Action Item 1 – The Legislation and Regulation Committee (committee) recommends altering the draft language for authorizing hospital central fill pharmacies to permit either a community pharmacy or a hospital pharmacy to perform the central fill function. (Attachment A)

Discussion: The board approved initiation of a rulemaking to authorize hospital central fill pharmacies. The draft presented for the informational hearing required that a hospital pharmacy perform the central fill function. Based on comment received at the informational hearing the committee recommended that the language be altered to permit either a community or a hospital pharmacy to perform central fill for a hospital pharmacy. The change will provide greater flexibility in designing central fill functions and will free valuable hospital space by permitting central fill functions to be located outside the hospital.

Action Item 2 – The committee recommends altering the draft language regarding common electronic prescription files to require pharmacies utilizing common electronic files to adopt policies ensuring that confidential medical information is disclosed appropriately. (Attachment B)

Discussion: The board approved a rulemaking to conform existing regulations on common electronic files to California law relating to confidential medical information. The draft of language presented at the informational hearing has not previously been presented to the board.

Action Item 3 – The committee recommends that the board direct staff to review existing regulations and submit a Section 100 rulemaking to conform existing regulations with legislative changes in the 2003 session.

Discussion: The 2003 legislative session has produced two bills making widespread changes to pharmacy law and will result in the need for updating existing board regulations. The Section 100 process is an abbreviated rulemaking procedure that allows relatively easy technical updates to existing regulations.

Action Item 4 – The committee recommends that the board sponsor a provision in the 2004 omnibus bill to eliminate the requirement that the supervising physician's name be on the label of a prescription issued under protocol by a nurse practitioner, nurse midwife, pharmacist, or physician assistant. (Attachment C)

Discussion: Existing law (Business and Professions Code 4076) requires the name of both the supervising physician and the name of the practitioner ordering the drug under protocol to be on the label attached to a dispensed prescription. This practice results in both pharmacies and patients contacting the supervising physician who typically has never seen the patient instead of contacting the practitioner ordering the drug. Eliminating the physician's name from the label will eliminate this possible confusion.

The attached draft language also adds a pharmacist operating under protocol to Section 4076. Pharmacists have authority to initiate and adjust drug therapy under protocol in a manner similar to that of these other practitioners and adding pharmacists to these provisions recognizes that authority.

Action Item 5 – The committee recommends that the board sponsor a provision in the 2004 omnibus bill to permit any pharmacist on duty to sign for the receipt of dangerous drugs or dangerous devices. (Attachment D)

Discussion: Existing law (Business and Professions Code 4059.5) requires the pharmacist-in-charge, if on duty, or a designated pharmacist to sign for the receipt of any delivery of dangerous drugs or dangerous devices. This change would free the pharmacist-in-charge from this responsibility which can safely be performed by any pharmacist. The attached draft text includes changes to existing law permitting the after hours delivery of drugs to a secure location that the board approved at its July 2003 meeting.

Action Item 6 – The committee recommends the board discuss new draft language permitting a pharmacist to serve as pharmacist-in-charge at two pharmacies and to take action as it deems appropriate. (Attachment E)

Discussion: The board has approved initiating a rulemaking to permit pharmacists to act as pharmacist-in-charge at two pharmacies. The committee conducted an informational hearing on draft language on September 11, 2003 and received substantial comment from interested parties on the draft. Specifically, the committee directed staff to submit a new draft that establishes some reasonable restriction on a geographic separation between two pharmacies with the same pharmacist-in-charge and that more clearly establish the central role of the pharmacist-in-charge. The attached draft includes a 50 mile restriction and clarifies that the pharmacist-in-charge must have actual control of pharmacy operations. The attached language also recasts the language allowing the designation of an interim pharmacist-in-charge per the discussion at the informational hearing. The committee wanted to submit the new draft and the central question of permitting a pharmacist to serve as PIC at two pharmacies for board discussion.

Action Item 7 – The committee recommends adopting the final version of the sterile compounding regulations. (Attachment F)

Discussion: The board approved the proposed sterile compounding standards at its April 2003 meeting with changes that required a 15-day comment period. Subsequent to that meeting the

Office of Administrative Law has determined that the board must ratify the final version of the regulation again after the close of a 15-day comment period. There is no opposition to the proposed regulations at this time.

NO ACTION

Recently Approved

Section 1775 et seq. – Citation and Fine
Summary: This regulation designates the executive officer as the issuing authority for citations and fines. The regulation also consolidates and recasts existing board regulations relating to citations and fines.
Status: Approved by OAL: September 11, 2003. Effective Date: October 11, 2003.

Pending Regulations

Section 1751 – Sterile Compounding
Summary: This regulation will establish guidelines for the compounding of sterile drug products.
Status: Awaiting final board vote.

Regulations Awaiting Notice

Section 1707.5 – Hospital Central Fill
Summary: This regulation will permit central refill operations for hospitals.
Status: Revised language referred to board for approval.

Section 1709.1 - Pharmacist-in-Charge at Two Locations
Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.
Status: Revised language referred for board discussion and appropriate action.

Section 1711 – Patient Notification
Summary: This regulation will modify the patient notification provisions of the board's quality assurance regulation to require notification to the patient if the drug was actually taken or if it resulting in a clinically significant delay in therapy.
Status: Awaiting notice.

Section 1715 – Pharmacy Self Assessment
Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.
Status: Informational Hearing Required

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records

Summary: This regulation will make any needed changes to board regulations to conform to changes in patient privacy laws.
Status: Awaiting notice

Section 1717.4 – Authentication of Electronic Prescriptions
Summary: This regulation will require pharmacists to authenticate electronic prescriptions.
Status: Awaiting notice

Section 1793.3 – "Clerk-Typist" Ratio
Summary: This regulation will eliminate the clerk/typist ratio.
Status: Informational hearing held, action deferred until January 2004 board meeting to accommodate staff workload and ongoing negotiations regarding a statutory revision to ancillary staff ratios.

Pending Legislation

Senate Bill 361 (Figueroa)

This bill is the board's sunset review legislation. The bill contains the recommendations from the Joint Legislative Sunset Review Committee that require statutory changes including:

- Adoption of NAPLEX and the MPJE.
- Add two public members to the board.
- Permit non-pharmacists to be board inspectors.
- Revision of pharmacy technician qualifications.

The bill also contains the board's omnibus items for 2003.

The bill was signed by the Governor on September 25, 2003. The bill was amended to require periodic evaluation of the NAPLEX and designates three of the pharmacist seats on the board as follows:

- A pharmacist who is a union member.
- A chain community pharmacy representative (more than 75 stores).
- An independent community pharmacy representative (four or fewer stores).

Status of Bills with a Board Position

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."
Board Position: **Support**
Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.
Board Position: **Support**
Status: Senate Rules Committee

AB 1363 (Berg) Establishes requirements for needle exchange programs.
Board Position: **Support**
Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy. Board Position: **Support**
Status: Two-year bill

SB 151 (Burton) Eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper resistant prescribing pad for all controlled substance prescriptions. Adds Schedule III drugs to CURES. The full text is included for your reference as Attachment B.
Board Position: **Support**
Status: Signed by the Governor (Chapter 406, Statutes of 2003)

SB 175 (Kuehl) Adds veterinary drugs to the definition of dangerous drugs.
Board Position: **Support**
Status: Signed by the Governor (Chapter 250, Statutes of 2003)

SB 393 (Aanestad) Permits "tech check tech" in hospitals.
Board Position: **Support if Amended**
Status: Two-year bill

SB 490 (Alpert) Establishes a statewide protocol for pharmacists dispensing emergency contraception.
Board Position: **Support**
Status: Signed by the Governor (Chapter 651, Statutes of 2003)

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.
Board Position: **Oppose**
Status: Two-year bill

SB 545 (Speier) Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. The author accepted amendments to resolve the boards opposition. These amendments include restoring the training requirement and eliminating restrictions on the consultation provided by the pharmacist.
Board Position: **Neutral**
Status: Signed by the Governor (Chapter 652, Statutes of 2003)

SB 774 (Vasconcellos) Eliminates the prescription requirement for hypodermic needles and syringes.
Board Position: **Support**
Status: Vetoed

Bills of Interest

AB 57 (Bates) Places MDMA into Schedule II.
Status: Assembly Inactive File

AB 186 (Correa) Makes technical changes to the Pharmacy Law relating to optometrists.
Status: Signed by the Governor (Chapter 426, Statutes of 2003)

AB 292 (Yee) Prohibits minors from acting as interpreters.
Status: Two-year bill

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.
Status: Two-year bill.

AB 1196 (Montanez) Permits nurse practitioners to order Schedule II drugs.
Status: Signed by the Governor (Chapter 748, Statutes of 2003)

SB 292 (Speier) Requires prescription labels to have a description of the drug.
Status: Signed by the Governor (Chapter 544, Statutes of 2003)

The text of bills signed by the Governor is included in Attachment G for your reference.

Quarterly Status Report on Committee Goals for 2002-03

For your information, an update of the Committee's progress in accomplishing its strategic objectives is attached to this report (Attachment H).

Meeting Summary for September 11, 2003

For your information the minutes from the September 11, 2003 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment I). The committee scheduled its next meeting for January 8, 2004 at 10:30 a.m.

Attachment A

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Board of Pharmacy
Hospital Central Fill

Amend Section 1710:

1710. Inpatient Hospital Pharmacy.

(a) ~~For purposes of Business and Professions Code Section 4111, an inpatient hospital pharmacy is a hospital pharmacy pursuant to Business and Professions Code Section 4029 which solely or predominantly furnishes drugs to inpatients of that hospital.~~ A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

(1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy,

(2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy,

(3) Each cassette or container meets the requirements of Business and Professions Code section 4076,

(4) Both pharmacies are responsible for ensuring that the order has been properly filled, and

(5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.

(6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4111, 4118 and 4380, Business and Professions Code.

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Attachment B

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BOARD OF PHARMACY
Draft Revisions For Informational Hearing
Confidentiality of Medical Information

§1717.1. Common Electronic Files.

(a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.
(b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.
(c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.
(d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
(e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information contained in those common electronic files.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

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Board of Pharmacy
Omnibus Item – Identification of the Prescriber

Amend Section 4076 of the Business and Professions Code, to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or ~~and~~, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a pharmacist who functions under a protocol as described in Section 4052, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, a pharmacist who functions under a protocol as described in Section 4052, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

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Board of Pharmacy
Omnibus Item – Delivery of Drugs

Amend Section 4059.5 of the Business and Professions Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must be delivered to the licensed premises and signed for and received by a pharmacist. ~~the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge.~~ Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.
(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices.
(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any person or entity receiving delivery of any dangerous drugs or devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.
(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.
(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.
(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge shall have access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.
(3) The secure storage facility shall have a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.
(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.
(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision shall leave documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

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Attachment E

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Board of Pharmacy
Draft Revisions For October 2003 Board Meeting
Pharmacist-In-Charge

§1709.1. Designation of ~~Pharmacist in Charge.~~ Pharmacist-In-Charge.

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles. ~~one pharmacy, except that a pharmacist may serve as a pharmacist-in-charge for two pharmacies if (1) the pharmacist-in-charge is the only pharmacist at each pharmacy and (2) the pharmacies do not have overlapping hours of business.~~
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the exemptee-in-charge ~~sole pharmacist~~ for a wholesaler~~, a medical device retailer~~ or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), ~~A~~ a pharmacy may~~, on an interim basis,~~ designate ~~as the interim pharmacist-in-charge~~ any ~~registered~~ pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. ~~or in the practice of pharmacy at the pharmacy involved.~~ The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a ~~the interim~~ pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
~~The interim basis shall not exceed 120 days.~~
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, 4330, 4331 and 4332, Business and Professions Code.

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State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: October 15, 2003

From: Paul Riches, Chief of Legislation and Regulation

Subject: Sterile Compounding Regulations

At its April 2003 meeting, the board approved new standards for compounding sterile injectable drug products. These regulations arose from Senate Bill 293 (Chapter 827, Statutes of 2001) which established special license requirements for pharmacies that compound sterile injectable drugs. The regulations were the result of over a year's worth of effort by the board and the pharmacy community. The changes adopted by the board at the April 2003 meeting required additional notice to comply with the Administrative Procedures Act. Subsequent to that action, the Office of Administrative Law ruled that rulemaking agencies must ratify the final version of proposed regulations after the completion of a notice period. Accordingly, the final text is before the board for ratification at this meeting. The draft presented to the board at this time is a consensus document with no known opposition.

Board of Pharmacy
Proposed Revisions to Title 16 CCR 1751 et seq.
Proposed Changes – July 30, 2003
Second 15 Day Notice

Article 7. Sterile Injectable Compounding

Amend Section 1751. Sterile Injectable Compounding Area

(a) The pharmacy shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

(1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.

(2) Walls, ceilings, and floors shall have cleanable, nonporous surfaces and be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.

(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.

(4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the Certification records must be retained for at least 3 years.

(5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(6) A sink with hot and cold running water shall be in accordance in Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.

(7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

NOTE
Authority cited: Section 4005, Business and Professions Code.
Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Add Section 1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients

(a) On and after January 1, 2005 this subdivision shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients. The aseptic processing of such products shall occur in one of the following environments:

(1) A class 100 laminar airflow hood within a class 10,000 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(2) A class 100 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(3) A barrier isolator that provides a class 100 environment for compounding.

(b) No sterile injectable product shall be prepared if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

(c) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

(d) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

(e) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Add Section 1751.02. Policies and Procedures

(a) Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to:

(1) Compounding, filling, and labeling of sterile injectable compounds..

(2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.

(3) Equipment and supplies.

(4) Training of staff in the preparation of sterile injectable products.

(5) Procedures for handling cytotoxic agents.

(6) Quality assurance program.

(7) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

(1) Immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

(3) Policies and procedures must address at least the following:

(A) Competency evaluation.

(B) Storage and handling of products and supplies.

(C) Storage and delivery of final products.

(D) Process validation.

(E) Personnel access and movement of materials into and near the controlled area.

(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
(J) Sterilization.
(K) End-product evaluation and testing.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.2. Labeling Requirements

In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:
a. Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
b. Name and concentrations of ingredients contained in the sterile injectable product.
c. Instructions for storage and handling.
d. All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly."

NOTE
Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.3. Record keeping Requirements

~~(a) In addition to the medication profile required by section 1707.1, pharmacies Pharmacies which both compound sterile injectable products for patients in skilled nursing facilities and patients receiving intravenous drug therapy in the home setting parenteral solutions and dispense those solutions shall have on the premises or readily accessible an immediately readily retrievable patient profile record for each patient being treated with compounded sterile injectable products. with parenteral therapy. In addition to existing record keeping requirements,~~

~~the. The following records shall be maintained when dispensing compounded sterile injectable products for patients in these care settings:~~

~~(a) Records of furnishing of all prescriptions and medical supplies;~~

~~(b) (1) Information relevant to the patient's parenteral sterile injectable drug therapy shall include but not be limited to:~~

~~(1) (A) Patient's body weight.~~

~~(2) (B) Primary diagnosis related to need for prescribed therapy; secondary diagnosis if available.~~

~~(3) (C) Summary of most recent hospitalization and/or previous history related to the diagnosis for which the sterile injectable drug is prescribed.~~

~~(4) Medication history, including current diet/medication regimen and drug/food allergies.~~

~~(c) (2) Progress notes documenting pharmacist contact with the patient or physician relative to compounded sterile injectable drug parenteral therapy.~~

~~(d) (3) Laboratory data relevant to the pharmacist's management of the patient's treatment with compounded sterile injectable drug parenteral therapy.~~

~~(b)~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

~~(c)~~(b) In addition to the records required by subdivisions (a) and (b), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:

(1) The training and competency evaluation of employees in sterile product procedures.

(2) Refrigerator and freezer temperatures.

(3) Certification of the sterile compounding environment.

(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

~~(d)~~(c) Pharmacies shall maintain records of process validation as required by Section 1751.7 (b) for three years.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.4. Attire

(a) When preparing cytotoxic agents, gowns and gloves shall be worn.

(b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

(1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.

(2) Cleanroom garb must be donned and removed outside the designated area.

(3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
(4) Head and facial hair must be kept out of the critical area or be covered.
(5) Gloves made of low-shedding materials are required.

(c) The requirements of this subdivision do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.5. Training of Staff, Patient, and Caregiver

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
(b) The pharmacist in charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
(e) Pharmacies that compound sterile injectable products from one or more non-sterile ingredients must comply with the following training requirements:

1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
(A) Aseptic technique.
(B) Pharmaceutical calculations and terminology.
(C) Sterile product compounding documentation.
(D) Quality assurance procedures.
(E) Aseptic preparation procedures.
(F) Proper gowning and gloving technique.
(G) General conduct in the controlled area.
(H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
(I) Sterilization techniques.
(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.6. Disposal of Waste Material

Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.7. Quality Assurance and Process Validation

(a) There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist in charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the sterile injectable medication preparation area.
(2) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
(3) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
(4) Steps to be taken in the event of a drug recall.
(5) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must successfully complete a validation process <u>on technique</u> before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used <u>in place of the actual product used during sterile preparation.</u> ~~to test the sterility of a final product and~~ <u>The validation process</u> shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process

changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Repeal Section 1751.8. Policies and Procedures

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Amend Section 1751.9. Reference Materials

There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Attachment G

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Assembly Bill No. 186

CHAPTER 426

An act to amend Sections 4059, 4060, and 4061 of the Business and Professions Code, and to amend Sections 11250 and 11251 of the Health and Safety Code, relating to optometrists.

[Approved by Governor September 20, 2003. Filed with Secretary of State September 22, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

AB 186, Correa. Optometrists: dangerous drugs and devices.

Existing law, the Pharmacy Law, authorizes a manufacturer, wholesaler, or pharmacy to furnish a dangerous drug or dangerous device to a physician, dentist, podiatrist, and veterinarian without a prescription when accompanied by sale and purchase records. Existing law also permits these persons to possess a controlled substance when in properly labeled stocked containers, and also authorizes the distribution of a dangerous drug or device as a complimentary sample only upon the written request of these persons. Existing law, the California Uniform Controlled Substances Act, authorizes the sale by designated persons of a controlled substance without a prescription to specified healing arts practitioners.

This bill would include optometrists in these provisions.

Existing law authorizes a pharmacist to furnish topical pharmaceutical agents to an optometrist.

The bill would instead authorize a pharmacist to furnish therapeutic pharmaceutical agents to an optometrist.

The people of the State of California do enact as follows:

SECTION 1. Section 4059 of the Business and Professions Code is amended to read:

4059. (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, or veterinarian, or to a laboratory under sales and purchase records that

correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Health Services. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Examining Committee of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary

food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

SEC. 2. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, optometrist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

SEC. 3. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, or veterinarian. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to a protocol described in Section 3502.1, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725 or 3502.1, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, or physician assistant shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity

of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, or physician assistant.

SEC. 4. Section 11250 of the Health and Safety Code is amended to read:

11250. (a) No prescription is required in case of the sale of controlled substances at retail in pharmacies by pharmacists to any of the following:

(1) Physicians.

(2) Dentists.

(3) Podiatrists.

(4) Veterinarians.

(5) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.

(6) Optometrist.

(b) In any sale mentioned in this article, there shall be executed any written order that may otherwise be required by federal law relating to the production, importation, exportation, manufacture, compounding, distributing, dispensing, or control of controlled substances.

SEC. 5. Section 11251 of the Health and Safety Code is amended to read:

11251. No prescription is required in case of sales at wholesale by pharmacies, jobbers, wholesalers, and manufacturers to any of the following:

(a) Pharmacies as defined in the Business and Professions Code.

(b) Physicians.

(c) Dentists.

(d) Podiatrists.

(e) Veterinarians.

(f) Other jobbers, wholesalers or manufacturers.

(g) Pharmacists acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurses acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistants acting within

the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107.

(h) Optometrists.

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Assembly Bill No. 747

CHAPTER 659

An act to amend Section 810 of the Business and Professions Code, and to amend Sections 14105.48, 19356, and 19805 of the Welfare and Institutions Code, relating to human services.

[Approved by Governor October 2, 2003. Filed with Secretary of State October 3, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

AB 747, Matthews. Human services: Medi-Cal.

(1) Existing law establishes the Department of Consumer Affairs that is comprised of various boards that license and regulate the profession under the board's jurisdiction. Existing law, by initiative statute, creates the Osteopathic Board of California and the State Board of Chiropractic Examiners with similar licensing and regulatory duties with respect to those professions.

Existing law authorizes a board to suspend or revoke a license if the licensee has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services, pursuant to which health care benefits are provided to public assistance recipients and certain other low-income persons, including dental benefits under the Denti-Cal element of the Medi-Cal program. Under existing law, the Director of Health Services is required to suspend the participation in the Medi-Cal program by a provider of services for conviction of any felony or any misdemeanor involving fraud.

This bill would require specified boards within the department, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners to convene disciplinary hearings to revoke a license if the licensee has more than one conviction, as defined, for any felony involving Medi-Cal fraud committed by the licensee in conjunction with the Medi-Cal program or the Denti-Cal element of the Medi-Cal program, and would require revocation unless there are mitigating circumstances. Conviction of the 2nd felony arising out of separate prosecutions would result in automatic suspension of the license. The bill would apply to a licensee with one or more convictions prior to January 1, 2004, in a specified manner. The bill would additionally require these boards to convene disciplinary hearings to

suspend or revoke a license if the licensee has one conviction, as defined, for any of the above activities.

(2) Under existing law, durable medical equipment is a covered benefit under the Medi-Cal program, subject to utilization controls.

This bill would revise the schedule of maximum allowable rates for durable medical equipment.

Under existing law, the department may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers, distributors, dispensers, or suppliers of appliances, durable medical equipment, medical supplies, and other product-type health care services for the purpose of obtaining the most favorable prices to the state and to assure adequate quality of the product or service, with certain exceptions. Existing law requires the department to establish a list of covered services and maximum allowable reimbursement rates for durable medical equipment.

This bill would authorize the department to require providers of durable medical equipment to appeal Medicare denials for dually eligible beneficiaries as a condition of Medi-Cal payment.

(3) Existing law requires the Department of Rehabilitation to suspend for the 2003–04 fiscal year the biennial rate adjustment for certain work-activity programs.

This bill would require the department to suspend the biennial rate adjustment until July 1, 2006.

(4) Existing law requires the Department of Rehabilitation to provide assistance and funding to independent living centers, which are nonprofit entities that provide services to individuals with disabilities. Existing law provides a formula for the allocation of funds appropriated by the Legislature to independent living centers.

Existing law authorizes the department to provide a funding advance in specified amounts to independent living centers that comply with certain accounting criteria established by the department.

This bill would authorize the department to provide a similar funding advance to any contractor or grantee receiving funds pursuant to the provisions governing independent living centers. The bill would require any grantee of a funding advance also to meet reporting criteria established by the department.

(5) This bill would incorporate additional changes in Section 810 of the Business and Professions Code proposed by SB 359 that would become operative only if SB 359 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. Section 810 of the Business and Professions Code is amended to read:

810. (a) It shall constitute unprofessional conduct and grounds for disciplinary action, including suspension or revocation of a license or certificate, for a health care professional to do any of the following in connection with his or her professional activities:

(1) Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss under a contract of insurance.

(2) Knowingly prepare, make, or subscribe any writing, with intent to present or use the same, or to allow it to be presented or used in support of any false or fraudulent claim.

(b) It shall constitute cause for revocation or suspension of a license or certificate for a health care professional to engage in any conduct prohibited under Section 1871.4 of the Insurance Code or Section 550 of the Penal Code.

(c) (1) It shall constitute cause for automatic suspension of a license or certificate issued pursuant to Chapter 4 (commencing with Section 1600), Chapter 5 (commencing with Section 2000), Chapter 6.6 (commencing with Section 2900), Chapter 7 (commencing with Section 3000), or Chapter 9 (commencing with Section 4000), or pursuant to the Chiropractic Act or the Osteopathic Act, if a licensee or certificate holder has been convicted of any felony involving Medi-Cal fraud committed by the licensee or certificate holder in conjunction with the Medi-Cal program, including the Denti-Cal element of the Medi-Cal program, pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code. The board shall convene a disciplinary hearing to determine whether or not the license or certificate shall be suspended, revoked, or some other disposition shall be considered, including, but not limited to, revocation with the opportunity to petition for reinstatement, suspension, or other limitations on the license or certificate as the board deems appropriate.

(2) It shall constitute cause for automatic suspension and for revocation of a license or certificate issued pursuant to Chapter 4 (commencing with Section 1600), Chapter 5 (commencing with Section 2000), Chapter 6.6 (commencing with Section 2900), Chapter 7 (commencing with Section 3000), or Chapter 9 (commencing with Section 4000), or pursuant to the Chiropractic Act or the Osteopathic Act, if a licensee or certificate holder has more than one conviction of any felony arising out of separate prosecutions involving Medi-Cal fraud committed by the licensee or certificate holder in conjunction with

the Medi-Cal program, including the Denti-Cal element of the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code. The board shall convene a disciplinary hearing to revoke the license or certificate and an order of revocation shall be issued unless the board finds mitigating circumstances to order some other disposition.

(3) It is the intent of the Legislature that paragraph (2) apply to a licensee or certificate holder who has one or more convictions prior to January 1, 2004, as provided in this subdivision.

(4) Nothing in this subdivision shall preclude a board from suspending or revoking a license or certificate pursuant to any other provision of law.

(5) ''Board,'' as used in this subdivision, means the Dental Board of California, the Medical Board of California, the Board of Psychology, the State Board of Optometry, the California State Board of Pharmacy, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners.

(6) ''More than one conviction,'' as used in this subdivision, means that the licensee or certificate holder has one or more convictions prior to January 1, 2004, and at least one conviction on or after that date, or the licensee or certificate holder has two or more convictions on or after January 1, 2004. However, a licensee or certificate holder who has one or more convictions prior to January 1, 2004, but who has no convictions and is currently licensed or holds a certificate after that date, does not have ''more than one conviction'' for the purposes of this subdivision.

(d) As used in this section, health care professional means any person licensed or certified pursuant to this division, or licensed pursuant to the Osteopathic Initiative Act, or the Chiropractic Initiative Act.

SEC. 1.5. Section 810 of the Business and Professions Code is amended to read:

810. (a) It shall constitute unprofessional conduct and grounds for disciplinary action, including suspension or revocation of a license or certificate, for a health care professional to do any of the following in connection with his or her professional activities:

(1) Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss under a contract of insurance.

(2) Knowingly prepare, make, or subscribe any writing, with intent to present or use the same, or to allow it to be presented or used in support of any false or fraudulent claim.

(b) It shall constitute cause for revocation or suspension of a license or certificate for a health care professional to engage in any conduct

prohibited under Section 1871.4 of the Insurance Code or Section 550 of the Penal Code.

(c) (1) It shall constitute cause for automatic suspension of a license or certificate issued pursuant to Chapter 4 (commencing with Section 1600), Chapter 5 (commencing with Section 2000), Chapter 6.6 (commencing with Section 2900), Chapter 7 (commencing with Section 3000), or Chapter 9 (commencing with Section 4000), or pursuant to the Chiropractic Act or the Osteopathic Act, if a licensee or certificate holder has been convicted of any felony involving fraud committed by the licensee or certificate holder in conjunction with providing benefits covered by worker's compensation insurance, or has been convicted of any felony involving Medi-Cal fraud committed by the licensee or certificate holder in conjunction with the Medi-Cal program, including the Denti-Cal element of the Medi-Cal program, pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code. The board shall convene a disciplinary hearing to determine whether or not the license or certificate shall be suspended, revoked, or some other disposition shall be considered, including, but not limited to, revocation with the opportunity to petition for reinstatement, suspension, or other limitations on the license or certificate as the board deems appropriate.

(2) It shall constitute cause for automatic suspension and for revocation of a license or certificate issued pursuant to Chapter 4 (commencing with Section 1600), Chapter 5 (commencing with Section 2000), Chapter 6.6 (commencing with Section 2900), Chapter 7 (commencing with Section 3000), or Chapter 9 (commencing with Section 4000), or pursuant to the Chiropractic Act or the Osteopathic Act, if a licensee or certificate holder has more than one conviction of any felony arising out of separate prosecutions involving fraud committed by the licensee or certificate holder in conjunction with providing benefits covered by worker's compensation insurance, or in conjunction with the Medi-Cal program, including the Denti-Cal element of the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code. The board shall convene a disciplinary hearing to revoke the license or certificate and an order of revocation shall be issued unless the board finds mitigating circumstances to order some other disposition.

(3) It is the intent of the Legislature that paragraph (2) apply to a licensee or certificate holder who has one or more convictions prior to January 1, 2004, as provided in this subdivision.

(4) Nothing in this subdivision shall preclude a board from suspending or revoking a license or certificate pursuant to any other provision of law.

(5) ''Board,'' as used in this subdivision, means the Dental Board of California, the Medical Board of California, the Board of Psychology, the State Board of Optometry, the California State Board of Pharmacy, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners.

(6) ''More than one conviction,'' as used in this subdivision, means that the licensee or certificate holder has one or more convictions prior to January 1, 2004, and at least one conviction on or after that date, or the licensee or certificate holder has two or more convictions on or after January 1, 2004. However, a licensee or certificate holder who has one or more convictions prior to January 1, 2004, but who has no convictions and is currently licensed or holds a certificate after that date, does not have ''more than one conviction'' for the purposes of this subdivision.

(d) As used in this section, health care professional means any person licensed or certified pursuant to this division, or licensed pursuant to the Osteopathic Initiative Act, or the Chiropractic Initiative Act.

SEC. 2. Section 14105.48 of the Welfare and Institutions Code is amended to read:

14105.48. (a) The department shall establish a list of covered services and maximum allowable reimbursement rates for durable medical equipment as defined in Section 51160 of Title 22 of the California Code of Regulations and the list shall be published in provider manuals. The list shall specify utilization controls to be applied to each type of durable medical equipment.

(b) Reimbursement for durable medical equipment, except wheelchairs and wheelchair accessories, shall be the lesser of (1) the amount billed pursuant to Section 51008.1 of Title 22 of the California Code of Regulations, or (2) an amount that does not exceed 80 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar item or service, or (3) the guaranteed acquisition cost negotiated by means of the contracting process provided for pursuant to Section 14105.3 plus a percentage markup to be established by the department.

(c) Reimbursement for wheelchairs and wheelchair accessories shall be the lesser of (1) the amount billed pursuant to Section 51008.1 of Title 22 of the California Code of Regulations, or (2) an amount that does not exceed 100 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar item or service, or (3) the guaranteed acquisition cost negotiated by means of

the contracting process provided for pursuant to Section 14105.3 plus a percentage markup to be established by the department.

(d) Reimbursement for all durable medical equipment billed to the Medi-Cal program utilizing codes with no specified maximum allowable rate shall be the lesser of (1) the amount billed pursuant to Section 51008.1 of Title 22 of the California Code of Regulations, or (2) the guaranteed acquisition cost negotiated by means of the contracting process provided for pursuant to Section 14105.3 plus a percentage markup to be established by the department, or (3) the actual acquisition cost plus a markup to be established by the department, or (4) the manufacturer's suggested retail purchase price reduced by a percentage discount not to exceed 20 percent, or (5) a price established through targeted product-specific cost containment provisions developed with providers.

(e) Reimbursement for all durable medical equipment supplies and accessories billed to the Medi-Cal program shall be the lesser of (1) the amount billed pursuant to Section 51008.1 of Title 22 of the California Code of Regulations, or (2) the acquisition cost plus a 23 percent markup.

(f) Any regulation in Division 3 of Title 22 of the California Code of Regulations that contains provisions for reimbursement rates for durable medical equipment shall be amended or repealed effective for dates of service on or after the date of the act adding this section.

(g) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code, actions under this section shall not be subject to the Administrative Procedure Act or to the review and approval of the Office of Administrative Law.

(h) The department shall consult with interested parties and appropriate stakeholders in implementing this section with respect to all of the following:

(1) Notifying the provider representatives of the proposed change.

(2) Scheduling at least one meeting to discuss the change.

(3) Allowing for written input regarding the change.

(4) Providing advance notice on the implementation and effective date of the change.

(i) The department may require providers of durable medical equipment to appeal Medicare denials for dually eligible beneficiaries as a condition of Medi-Cal payment.

SEC. 3. Section 19356 of the Welfare and Institutions Code is amended to read:

19356. (a) The department shall adopt regulations to establish rates for work-activity program services subject to the approval of the Department of Finance. The regulations shall provide for an equitable

ratesetting procedure in which each specific allowable service, activity, and provider administrative cost comprising an overall habilitation service, as determined by the department, reflects the reasonable cost of service. Reasonable costs shall be determined biennially by the department, subject to audit at the discretion of the department.

(b) It is the intent of the Legislature that, commencing July 1, 1996, the department establish rates for both habilitation services and vocational rehabilitation work-activity programs pursuant to subdivision (a). Nothing in this subdivision shall preclude the subsequent amendment or adoption of regulations pursuant to subdivision (a).

(c) Notwithstanding any other provision of law, the department shall suspend, until July 1, 2006, the biennial rate adjustment for work-activity programs.

(d) Commencing July 1, 2003, the rates paid to work-activity programs pursuant to this section shall be reduced by 5 percent.

SEC. 4. Section 19805 of the Welfare and Institutions Code is amended to read:

19805. (a) The Department of Rehabilitation may advance to an independent living center an amount, each month, not in excess of one-twelfth of the annual allocation for the independent living center.

(b) The Department of Rehabilitation may advance to any contractor or grantee receiving funds pursuant to this chapter an amount, each month, not in excess of one-twelfth of the annual allocation for the contractor or grantee.

(c) To obtain approval by the department for a funding advance pursuant to this section, a grantee of a funding advance shall meet accounting and reporting criteria established by the Department of Rehabilitation.

SEC. 5. Section 1.5 of this bill incorporates amendments to Section 810 of the Business and Professions Code proposed by both this bill and SB 359. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends Section 810 of the Business and Professions Code, and (3) this bill is enacted after SB 359, in which case Section 1 of this bill shall not become operative.

O

Assembly Bill No. 1196

CHAPTER 748

An act to amend Section 2836.1 of the Business and Professions Code, and to amend, repeal, and add Section 11165 of the Health and Safety Code, relating to drugs.

[Approved by Governor October 9, 2003. Filed with Secretary of State October 10, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1196, Montanez. Drugs.

Existing law, the Nursing Practice Act, licenses and regulates nurse practitioners and authorizes a nurse practitioner to furnish drugs or devices that are classified as Schedule III to Schedule V controlled substances under the California Uniform Controlled Substances Act, subject to certain conditions. Existing law makes a violation of the act a misdemeanor.

This bill would expand these provisions to include drugs or devices that are classified as Schedule II controlled substances under the California Uniform Controlled Substances Act. The bill would establish additional requirements for a nurse practitioner who is authorized to furnish drugs or devices. The bill would require nurse practitioners to complete a continuing education course including Schedule II controlled substances based on standards developed by the board.

Existing law provides for the electronic monitoring of prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program. The program is contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund.

This bill would add the Board of Registered Nursing Fund to the fund list.

By increasing the scope of the Nursing Practice Act, the violation of which is a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would incorporate additional changes to Section 11165 of the Health and Safety Code proposed by SB 151, to be operative only if this bill and SB 151 are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. Section 2836.1 of the Business and Professions Code is amended to read:

2836.1. Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon under any of the following circumstances:

(1) When furnished or ordered incidental to the provision of family planning services.

(2) When furnished or ordered incidental to the provision of routine health care or prenatal care.

(3) When rendered to essentially healthy persons.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical

presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g) (1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed (1) at least six month's physician and surgeon-supervised experience in the furnishing or ordering of drugs or devices and (2) a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled substances based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term ''furnishing'' in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) ‘‘Drug order’’ or ‘‘order’’ for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to ‘‘prescription’’ in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 2. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

(b) The CURES pilot project shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision, shall not be disclosed, sold, or transferred to any third party.

(c) This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 4. Section 11165 is added to the Health and Safety Code, to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of

California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 5. Sections 3 and 4 of this bill incorporate amendments to Section 11165 of the Health and Safety Code proposed by both this bill and SB 151. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends or makes other changes to Section 11165 of the Health and Safety Code, and (3) this bill is enacted after SB 151, in which case Section 2 of this bill and Section 17 of SB 151 shall not become operative.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the

only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Senate Bill No. 151

CHAPTER 406

An act to amend Sections 11165.1 and 11166 of, to amend and repeal Sections 11162, 11168, and 11169 of, to amend, repeal, and add Sections 11159.2, 11161, 11164, 11165, 11167, 11167.5, and 11190 of, to add Sections 11029.5, 11161.5, 11161.7, 11162.1, and 11162.6 to, and to add, repeal, and add Section 11164.1 to, the Health and Safety Code, relating to controlled substances.

[Approved by Governor September 16, 2003. Filed with Secretary of State September 17, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 151, Burton. Controlled substances: Schedule II.

Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with specified requirements, one of which is that prescriptions for Schedule II controlled substances shall be prepared on triplicate prescription blanks issued by the Department of Justice. Existing law also provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program, as specified. The CURES program is scheduled to become inoperative on July 1, 2008, and repealed on January 1, 2009. Existing law provides that a violation of any of these provisions is generally a misdemeanor.

This bill would, on and after July 1, 2004, eliminate the triplicate prescription requirement for Schedule II controlled substances and would, on and after January 1, 2005, require prescribers of Schedule II controlled substances to meet the same prescription requirements imposed with respect to other prescribable controlled substances, as specified. The bill would, on and after January 1, 2005, require prescriptions for any controlled substance to be issued on controlled substance prescription forms obtained from a security printer approved by the Board of Pharmacy, as specified. Between July 1, 2004, and January 1, 2005, these prescriptions would be permitted using either the triplicate form or the security forms. The bill would make the CURES program applicable to Schedule III drugs if there is adequate funding and would also provide for the indefinite continuation of the CURES program by deleting its repeal date. The bill would make it a crime to counterfeit a controlled substance prescription; knowingly possess a

counterfeited controlled substance prescription; or obtain under false pretenses, or fraudulently produce, a controlled substance prescription, as specified. By creating new crimes, the bill would impose a state-mandated local program.

The bill would also revise provisions relating to electronically transmitted prescriptions and would add provisions authorizing pharmacies to dispense certain prescriptions from out-of-state prescribers, as specified. The bill would make conforming changes to related provisions.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would incorporate additional changes to Section 11165 of the Health and Safety Code proposed by AB 1196, to be operative only if this bill and AB 1196 are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature in enacting this act to do the following:

(a) Increase patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.

(b) Provide that the forms required by the act for controlled substance prescriptions may be used to prescribe any prescription drug or device.

SEC. 2. Section 11029.5 is added to the Health and Safety Code, to read:

11029.5. ''Security printer'' means a person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

SEC. 3. Section 11159.2 of the Health and Safety Code is amended to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall not be subject to Section 11164.

(b) (1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally ill by the words ''11159.2 exemption.''

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(d) For purposes of this section, ''terminally ill'' means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(e) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 3.5. Section 11159.2 is added to the Health and Safety Code, to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words ''11159.2 exemption.''

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, ''terminally ill'' means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 4. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor.

(b) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks in the practitioner's possession at a time set in the order and shall direct the Department of Justice to withhold prescription blanks from the practitioner. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (c) and (f) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(c) The order provided by subdivision (b) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting

attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(d) The defendant may elect to challenge the order issued under subdivision (b) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (c) and any other evidence otherwise admissible at the preliminary examination.

(e) If the practitioner has not moved to vacate the order issued under subdivision (b) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (b) shall be vacated.

(f) Notwithstanding subdivision (e), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (b).

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 5. Section 11161 is added to the Health and Safety Code, to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks or controlled substance prescription forms in the practitioner's possession at a time set in the order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect

until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks or controlled substance prescription forms with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on July 1, 2004.

SEC. 6. Section 11161.5 is added to the Health and Safety Code, to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy.

(b) The Board of Pharmacy may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The applicant shall also provide fingerprints, in a manner specified by the Board of Pharmacy, for the purpose of completing state and federal criminal background checks.

(c) Prior to approving a security printer application, the Board of Pharmacy shall submit a copy of the application to the Department of Justice; the Department of Justice may, within 30 calendar days of receipt of the application from the Board of Pharmacy, deny the security printer application.

(d) The Board of Pharmacy or the Department of Justice may deny a security printer application on any of the following grounds:

(1) The applicant has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

(e) The Board of Pharmacy shall maintain a list of approved security printers and the Board of Pharmacy shall make this information available to prescribers and other appropriate government agencies, including the Department of Justice.

(f) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(g) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(h) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(i) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(j) (1) The Board of Pharmacy or the Department of Justice may revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the Board of Pharmacy or the Department of Justice revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(k) Security printer applicants may appeal a denial or revocation by the Board of Pharmacy to the full board in a public meeting of the Board of Pharmacy.

SEC. 7. Section 11161.7 is added to the Health and Safety Code, to read:

11161.7. (a) When a prescriber's authority to prescribe controlled substances is restricted by civil, criminal, or administrative action, or by an order of the court issued pursuant to Section 11161, the law enforcement agency or licensing board that sought the restrictions shall provide the name, category of licensure, license number, and the nature of the restrictions imposed on the prescriber to security printers, the Department of Justice, and the Board of Pharmacy.

(b) The Board of Pharmacy shall make available the information required by subdivision (a) to pharmacies and security printers to prevent the dispensing of controlled substance prescriptions issued by the prescriber and the ordering of additional controlled substance prescription forms by the restricted prescriber.

SEC. 8. Section 11162 of the Health and Safety Code is amended to read:

11162. (a) The prescription blanks shall be printed on distinctive paper, the serial number of the group being shown on each form, and each form being serially numbered. The prescription blanks shall bear the preprinted name, address, and category of professional licensure of the practitioner to whom they are issued, and the federal registry number for controlled substances.

(b) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 9. Section 11162.1 is added to the Health and Safety Code, to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive ''void'' pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word ''void'' shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words ''California Security Prescription.''

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall either (A) contain a statement printed on the bottom of the prescription blank that the ''Prescription is void if more than one controlled substance prescription is written per blank'' or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the ''Prescription is void if the number of drugs prescribed is not noted.''

(9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

(10) A check box indicating the prescriber's order not to substitute.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 10. Section 11162.6 is added to the Health and Safety Code, to read:

11162.6. (a) Every person who counterfeits a controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail for not more than one year, by a fine not

exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(b) Every person who knowingly possesses a counterfeited controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(c) Every person who attempts to obtain or obtains a controlled substance prescription form under false pretenses shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(d) Every person who fraudulently produces controlled substance prescription forms shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(e) This section shall become operative on July 1, 2004.

SEC. 11. Section 11164 of the Health and Safety Code is amended to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice. Each prescription shall be prepared in triplicate, signed by the prescriber, and shall contain, either typewritten or handwritten by the prescriber or his or her employee, the date, name, and address of the person for whom the controlled substance is prescribed, the name, quantity, and strength of the controlled substance prescribed, directions for use, and the address, category of professional licensure, and the federal controlled substance registration number of the prescriber. The original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription. The duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled and the signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled. Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the

prescription the address of the patient. A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction. The prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.

(b) Each prescription for a controlled substance classified in Schedule III, IV, or V, except as authorized by subdivision (c), shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules III and IV, the signature and date shall be wholly written in ink in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or

electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding any provision of subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 12. Section 11164 is added to the Health and Safety Code, to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) (1) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice or on a controlled substance prescription form that meets the requirements of Section 11162.1.

(2) Each prescription shall be signed by the prescriber and shall contain, either typewritten or handwritten by the prescriber or his or her agent, the date, name, and address of the person for whom the controlled substance is prescribed; the name, quantity, strength, and directions for use of the controlled substance prescribed; and the address, category of professional licensure, and federal controlled substance registration number of the prescriber.

(3) If the prescriber uses an official prescription form issued by the Department of Justice, the original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription; the duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled, and the

signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled.

(4) Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient.

(5) A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction; the prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.

(b) Each prescription for a controlled substance classified in Schedule III, IV, or V, except as authorized by subdivision (c), shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules III and IV, the signature and date shall be written in ink in the handwriting of the prescriber.

(2) (A) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber.

(B) The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand.

(C) Notwithstanding any other provision in this section, the prescriber's address, telephone number, category of professional licensure, and federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed; if the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an agent acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) (1) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included

in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the hard copy record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) This section shall become operative on July 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 13. Section 11164 is added to the Health and Safety Code, to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(e) This section shall become operative on January 1, 2005.

SEC. 14. Section 11164.1 is added to the Health and Safety Code, to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 15. Section 11164.1 is added to the Health and Safety Code, to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements

for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II and Schedule III controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2005.

SEC. 16. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that

patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 16.5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from

the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 17. Section 11165 is added to the Health and Safety Code, to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent

upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Date of issue of the prescription.
(8) Date of dispensing of the prescription.
(e) This section shall become operative on January 1, 2005.

SEC. 17.5. Section 11165 is added to the Health and Safety Code, to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 18. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II or Schedule III controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II or Schedule III controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 19. Section 11166 of the Health and Safety Code is amended to read:

11166. No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

SEC. 20. Section 11167 of the Health and Safety Code is amended to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in the loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all of the information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.

(c) The prescriber provides a triplicate prescription, completed as provided by subdivision (a) of Section 11164, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a written, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 21. Section 11167 is added to the Health and Safety Code, to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in the loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all of the information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a triplicate prescription form or a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on July 1, 2004, and shall remain in effect until January 1, 2005, at which time it is repealed.

SEC. 22. Section 11167 is added to the Health and Safety Code, to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

SEC. 23. Section 11167.5 of the Health and Safety Code is amended to read:

11167.5. (a) An order for a controlled substance classified in Schedule II in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription. Prior to filling the prescription, the pharmacist shall reduce it to writing in ink or indelible pencil in the handwriting of the pharmacist upon an official prescription form issued by the Department of Justice for that purpose. The prescriptions shall be prepared in triplicate and shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed facility or home health agency providing hospice care in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, and federal controlled substance registration number of the prescriber. The duplicate shall be retained by the pharmacist, and the triplicate shall be forwarded to the prescriber by the end of the month in which the prescription was issued. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the signature of the pharmacist, the name and address of the pharmacy, and the signature of the person who received the controlled substance for the licensed facility or home health agency providing hospice care and shall be forwarded by the pharmacist to the Department of Justice at the end of the month in which the prescription was filled. A skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone order, chart order, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) For the purposes of this section, ''hospice care'' means interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care.

(c) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 24. Section 11167.5 is added to the Health and Safety Code, to read:

11167.5. (a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted

prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) This section shall become operative on July 1, 2004.

SEC. 25. Section 11168 of the Health and Safety Code is amended to read:

11168. (a) The prescription book containing the prescriber's copies of prescriptions issued shall be retained by the prescriber which shall be preserved for three years.

(b) This section shall remain in effect only until January 1, 2008, and as of that date is repealed.

SEC. 26. Section 11169 of the Health and Safety Code is amended to read:

11169. (a) When codeine, or dihydrocodeinone or tincture opii camphorata (paregoric) is not combined with other medicinal ingredients, it shall be prescribed on the official triplicate blanks.

(b) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 27. Section 11190 of the Health and Safety Code is amended to read:

11190. Every practitioner, other than a pharmacist, who issues a prescription, or dispenses or administers a controlled substance

classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(a) The name and address of the patient.

(b) The date.

(c) The character, including the name and strength, and quantity of controlled substances involved.

The prescriber's record shall show the pathology and purpose for which the prescription is issued, or the controlled substance administered, prescribed, or dispensed.

This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 28. Section 11190 is added to the Health and Safety Code, to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance is administered or prescribed.

(c) (1) For each prescription for a Schedule II controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) Pharmacy prescription number, license number, and federal controlled substance registration number.

(D) NDC (National Drug Code) number of the controlled substance dispensed.

(E) Quantity of the controlled substance dispensed.

(F) ICD-9 (diagnosis code), if available.

(G) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hard copy or electronic form.

(d) This section shall become operative on July 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 29. Section 11190 is added to the Health and Safety Code, to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) Pharmacy prescription number, license number, and federal controlled substance registration number.

(D) NDC (National Drug Code) number of the controlled substance dispensed.

(E) Quantity of the controlled substance dispensed.

(F) ICD-9 (diagnosis code), if available.

(G) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hard copy or electronic form.

(d) This section shall become operative on January 1, 2005.

SEC. 30. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 31. Sections 16.5 and 17.5 of this bill incorporate changes to Section 11165 of the Health and Safety Code proposed by both this bill and AB 1196. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends or makes other changes to Section 11165 of the Health and Safety Code, and (3) this bill is enacted after AB 1196, in which case Sections 16 and 17 of this bill shall not become operative.

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Senate Bill No. 175

CHAPTER 250

An act to amend Sections 4022, 4067, 4170, 4171, and 4175 of the Business and Professions, relating to veterinary drugs.

[Approved by Governor September 1, 2003. Filed with Secretary of State September 2, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 175, Kuehl. Veterinary drugs: prescriptions by veterinarians.

(1) Existing law, the Pharmacy Law, defines a dangerous drug but excludes properly labeled veterinary drugs from the definition.

This bill would modify this definition to delete the exception for veterinary drugs.

(2) Existing law authorizes specified licensed individuals to prescribe dangerous drugs and authorizes each licensing entity to enforce the provisions of the Pharmacy Law regarding the prescription of dangerous drugs.

This bill would authorize a licensed veterinarian to prescribe a dangerous drug and would authorize the Veterinary Medical Board to enforce the provisions of the Pharmacy Law regarding the prescription of dangerous drugs.

(3) Existing law requires the California State Board of Pharmacy to notify the appropriate licensing entity if the board receives a complaint relating to dangerous drugs dispensed by a prescriber.

This bill would require the board to notify the Veterinary Medical Board if it receives a complaint relating to dangerous drugs dispensed by a veterinarian.

(4) Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4022 of the Business and Professions Code is amended to read:

4022. ''Dangerous drug'' or ''dangerous device'' means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: ''Caution: federal law prohibits dispensing without prescription,'' ''Rx only,'' or words of similar import.

(b) Any device that bears the statement: ''Caution: federal law restricts this device to sale by or on the order of a ____,'' ''Rx only,'' or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

SEC. 2. Section 4067 of the Business and Professions Code is amended to read:

4067. (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the

Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section, ''good faith prior examination'' includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

SEC. 3. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who

functions pursuant to Section 3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) ''Prescriber,'' as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

SEC. 4. Section 4171 of the Business and Professions Code is amended to read:

4171. (a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

SEC. 5. Section 4175 of the Business and Professions Code is amended to read:

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Veterinary Medical Board, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified

nurse-midwives, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Senate Bill No. 292

CHAPTER 544

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 27, 2003. Filed with Secretary of State September 29, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 292, Speier. Pharmacy: prescription labels.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy. Under the Pharmacy Law, a pharmacist is required to dispense a prescription in a container that is correctly labeled. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

Commencing January 1, 2006, this bill would require the label to have a physical description of the drug, including its color, shape, and any identification code appearing on the tablets or capsules. The bill would make certain exceptions to the bill's requirements, including an exemption for a new drug in its first 120 days on the market and for 90 days during which the national reference file has no description. The bill would provide that this requirement not go into effect if the board adopts regulations containing the requirement prior to January 1, 2006. Because a knowing violation of the bill would be a misdemeanor, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber and, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Senate Bill No. 361

CHAPTER 539

An act to amend Sections 4001, 4002, 4003, 4008, 4062, 4200, 4202, 4312, 4400, and 4403 of, and to add Sections 4083, 4106, 4200.2, 4200.3, 4200.4, 4314, and 4315 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 25, 2003. Filed with Secretary of State September 26, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 361, Figueroa. Pharmacy: administration and enforcement.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy within the Department of Consumer Affairs. Under existing law, the board is authorized to appoint an executive director to exercise the powers and perform the duties delegated by the board. The law makes these provisions inoperative on July 1, 2004, and repeals them on January 1, 2005. Under existing law, the board consists of 11 members, 2 of whom are public members appointed by the Governor.

This bill would delete these inoperative and repeal dates and would extend the operation of these provisions to make them inoperative on July 1, 2008, and repeal them on January 1, 2009. The bill would also increase the board membership to 13 by adding 2 more public members appointed by the Governor. The bill would also specify that one of the pharmacist appointees be a member of a labor union representing pharmacists, that one practice in an independent community pharmacy setting, and that another practice in a chain community pharmacy setting.

Existing law authorizes the board to employ inspectors of pharmacy. These inspectors are required to be pharmacists if their principal duties are either inspecting or investigating pharmacies or pharmacists or supervising other inspectors of pharmacy.

This bill would delete the requirement that certain inspectors of pharmacy must be pharmacists. The bill would authorize inspectors to issue a written order of correction and the executive officer, or his or her designee, to issue a letter of admonishment, directing a licensee to comply with the Pharmacy Law or related regulations. The bill would require an order of correction or a letter of admonishment to contain certain information, including the process for a licensee to contest the order or letter. The bill would require a licensee to have readily available on the pharmacy premises a copy of any order of correction or letter of

admonishment issued against it in the prior 3 years, and a related corrective plan of action. The bill would provide that an order of correction would not be a public record, except as specified.

This bill would authorize the board to issue a citation for a violation of the Pharmacy Law or related regulations, with a fine of up to $2,500 and an order of abatement, which may require a person to demonstrate how future compliance will be accomplished.

Existing law sets forth certain educational, training, and examination requirements that an applicant for a pharmacist license must meet.

This bill would revise the examination requirements, as specified, and would require the board to develop a Multi-State Pharmacy Jurisprudence Examination for California that meets certain guidelines and to review the examination process. The bill would prohibit an applicant who failed the national examination from retaking it for a designated time period.

Existing law requires an applicant for a pharmacy technician certification to meet certain education requirements.

This bill would revise those education requirements.

The Pharmacy Law makes a violation of its provisions a crime.

Because this bill would create new requirements for licensees under that law, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a ''chain community pharmacy'' means a chain of 75 or more stores in California under the same ownership, and an ''independent community pharmacy'' means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 2. Section 4002 of the Business and Professions Code is amended to read:

4002. (a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.

(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Seven members of the board constitute a quorum.

SEC. 3. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 4. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting

inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

SEC. 5. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

SEC. 6. Section 4083 is added to the Business and Professions Code, to read:

4083. (a) An inspector may issue an order of correction to a licensee directing the licensee to comply with this chapter or regulations adopted pursuant to this chapter.

(b) The order of correction shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statute or regulations violated.

(c) The order of correction shall inform the licensee that within 30 days of service of the order of correction, the licensee may do either of the following:

(1) Submit a written request for an office conference with the board's executive officer to contest the order of correction.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the licensee's legal counsel or authorized representative may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the order of correction.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the order of correction. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the order of correction.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the order of correction.

(2) Comply with the order of correction and submit a written corrective action plan to the inspector documenting compliance. If an office conference is not requested pursuant to this section, compliance with the order of correction shall not constitute an admission of the violation noted in the order of correction.

(d) The order of correction shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date of issuance of the order of correction.

(f) Nothing in this section shall in any way limit the board's authority or ability to do any of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Issue a letter of admonishment pursuant to Section 4315.

(3) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

(g) Unless a writ of mandate is filed, a citation issued, a letter of admonishment issued, or a disciplinary proceeding instituted, an order of correction shall not be considered a public record and shall not be disclosed pursuant to a request under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

SEC. 7. Section 4106 is added to the Business and Professions Code, to read:

4106. For purposes of license verification, a person may rely upon a printout from the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

SEC. 8. Section 4200 of the Business and Professions Code is amended to read:

4200. (a) The board shall license as a pharmacist, and issue a certificate to, any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the applicant has received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has had 1,500 hours of pharmaceutical experience in accordance with regulations adopted by the board.

(A) ‘‘Pharmaceutical experience,’’ constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly related to the selling of drugs, compounding physician’s prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.

(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

SEC. 9. Section 4200.2 is added to the Business and Professions Code, to read:

4200.2. When developing the Multi-State Pharmacy Jurisprudence Examination for California, the board shall include all of the following:

(a) Examination items to demonstrate the candidate’s proficiency in patient communication skills.

(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.

SEC. 10. Section 4200.3 is added to the Business and Professions Code, to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Examination Resources of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the

examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall report to the Joint Legislative Sunset Review Committee and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 11. Section 4200.4 is added to the Business and Professions Code, to read:

4200.4. An applicant who fails the national examination may not retake the examination for at least 90 days or for a period established by regulations adopted by the board in consultation with the Office of Examination Resources of the department.

SEC. 12. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) An applicant for registration as a pharmacy technician shall be issued a certificate of registration if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education or a school of pharmacy recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician certificate of registration must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the registration of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for registration as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of registration, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a registration issued pursuant to this section on any ground specified in Section 4301.

SEC. 13. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may cancel the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) In the event that the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an

order from the superior court in the county in which the wholesaler, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, or veterinary food-animal drug retailer.

(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, ‘‘closed’’ means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

SEC. 14. Section 4314 is added to the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

SEC. 15. Section 4315 is added to the Business and Professions Code, to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative

Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

SEC. 16. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for an out-of-state drug distributor’s license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

SEC. 17. Section 4403 of the Business and Professions Code is amended to read:

4403. The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

SEC. 18. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Senate Bill No. 490

CHAPTER 651

An act to amend Section 4052 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 1, 2003. Filed with Secretary of State October 1, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 490, Alpert. Pharmacy: prescriptions.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for regulating the practice of pharmacy. A knowing violation of the Pharmacy Law is a crime. Under that law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law authorizes a pharmacist to initiate emergency contraception drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice.

This bill would also authorize a pharmacist to furnish emergency contraception drug therapy in accordance with a standardized procedure or protocol developed and approved by both the board and the Medical Board of California, in consultation with specified entities. The bill would require a pharmacist to complete a specified training program before performing emergency contraception drug therapy. Because a violation of this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would also incorporate additional changes to Section 4052 of the Business and Professions Code proposed by SB 545 that would become operative only if SB 545 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception consisting of at least one hour of approved continuing education on emergency contraception drug therapy.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 1.5. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide

written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both

the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 2. Section 1.5 of this bill incorporates amendments to Section 4052 of the Business and Professions Code proposed by both this bill and SB 545. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends Section 4052 of the Business and Profession Code, and (3) this bill is enacted after SB 545, in which case Section 1 of this bill shall not become operative.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Senate Bill No. 545

CHAPTER 652

An act to amend Section 4052 of, and to add Section 682 to, the Business and Professions Code, relating to pharmacists.

[Approved by Governor October 1, 2003. Filed with Secretary of State October 1, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 545, Speier. Emergency contraception drug therapy.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy. Existing law requires a pharmacist to provide consultation when furnishing drugs, with certain exceptions, and the board has set forth specific requirements applicable to the provision of consultation and the maintenance of patient medication records. Existing law authorizes a pharmacist, in addition to other functions, to initiate emergency contraception drug therapy if the pharmacist has completed a training program on emergency contraception and certain other conditions are met.

This bill would instead authorize the pharmacist to furnish emergency contraception drug therapy subject to those conditions and would revise the training requirement. The bill would prohibit a pharmacist from requiring a patient to provide individually identifiable medical information, except as specified. The bill would also prohibit a pharmacist, or his or her employer or agent, from charging a separate consultation fee for the initiation of emergency contraception drug therapy, but would authorize an administrative fee not to exceed $10 above the retail cost of the drug. The bill would require a pharmacist, upon request, to disclose the total retail drug price for emergency contraception drug therapy.

Existing law sets forth certain requirements and prohibitions for health care providers.

This bill would prohibit an individual issuing a prescription or order for emergency contraception drug therapy through contact with a patient over the phone or through electronic means from charging an administrative fee of more than $10.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. All other violations of that law are infractions unless otherwise indicated.

Because this bill would create new prohibitions on pharmacists, the violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would also incorporate additional changes to Section 4052 of the Business and Professions Code proposed by SB 490 that would become operative only if SB 490 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to ensure equality of access to pharmaceuticals for the women of California. In ensuring that access, the Legislature intends to eliminate barriers relating to women obtaining emergency contraception.

SEC. 2. Section 682 is added to the Business and Professions Code, to read:

682. An individual authorized to prescribe emergency contraception who issues a prescription or order for emergency contraception drug therapy as a result of a patient contact by telephone or electronic means may not charge an administrative fee or fees totaling more than ten dollars ($10) for emergency contraception drug therapy services. This limitation is not intended to interfere with other contractually agreed-upon terms between an individual prescriber and a health care service plan, insurer, or disability insurer for payment directly to the prescriber by the plan or insurer.

SEC. 3. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber’s order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols

developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice, subject to the following requirements:

(A) Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(B) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay

for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are covered or insured and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(C) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 3.5. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug

regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with

the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully

completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 4. Section 3.5 of this bill incorporates amendments to Section 4052 of the Business and Professions Code proposed by both this bill and SB 490. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends Section 4052 of the Business and Professions Code, and (3) this bill is enacted after SB 490, in which case Section 3 of this bill shall not become operative.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Senate Bill No. 907

CHAPTER 485

An act to amend Sections 101, 144, 146, and 149 of, and to add and repeal Chapter 8.2 (commencing with Section 3610) of Division 2 of, the Business and Professions Code, and to amend Section 13401.5 of the Corporations Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor September 22, 2003. Filed with Secretary of State September 22, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 907, Burton. Professions and vocations: naturopathic doctors.

(1) Existing law establishes boards and bureaus within the Department of Consumer Affairs that are responsible for licensing and regulating persons practicing various healing arts disciplines.

This bill would establish, until July 1, 2009, the Naturopathic Doctors Act, to be administered by the Bureau of Naturopathic Medicine created within the Department of Consumer Affairs. The bill would specify various standards for the licensure and regulation of naturopathic medicine that the bureau would enforce. The bill would create the Naturopathic Doctor's Fund, and would require fees collected by the bureau to be deposited into the fund. The bill would specify that the moneys in the fund are available to the bureau only upon appropriation by the Legislature, but it would appropriate all money other than specified revenue received and credited to the fund in the 2003–04 fiscal year to the bureau to implement the act's provisions. The bill would make the provisions of the act relating to the fund operative on January 1, 2004, but would make the remainder of the act operative on July 1, 2004. The bill would require the department to certify that sufficient funds are available in the Naturopathic Doctor's Fund prior to implementation. The bill would make additional related changes.

(2) Existing law requires specified regulatory boards within the department to obtain fingerprints from a licensing applicant to conduct a criminal history check.

This bill would extend this requirement to the Bureau of Naturopathic Medicine, the Contractors' State License Board, and the Structural Pest Control Board.

(3) Because the bill would make the violation of certain of its provisions a crime, it would impose a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(5) This bill would incorporate additional changes in Section 13401.5 of the Corporations Code proposed by AB 123 that would become operative only if AB 123 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 101 of the Business and Professions Code is amended to read:

101. The department is comprised of:

(a) The Dental Board of California.

(b) The Medical Board of California.

(c) The State Board of Optometry.

(d) The California State Board of Pharmacy.

(e) The Veterinary Medical Board.

(f) The California Board of Accountancy.

(g) The California Architects Board.

(h) The Bureau of Barbering and Cosmetology.

(i) The Board for Professional Engineers and Land Surveyors.

(j) The Contractors' State License Board.

(k) The Bureau for Private Postsecondary and Vocational Education.

(*l*) The Structural Pest Control Board.

(m) The Bureau of Home Furnishings and Thermal Insulation.

(n) The Board of Registered Nursing.

(o) The Board of Behavioral Sciences.

(p) The State Athletic Commission.

(q) The Cemetery and Funeral Bureau.

(r) The State Board of Guide Dogs for the Blind.

(s) The Bureau of Security and Investigative Services.

(t) The Court Reporters Board of California.

(u) The Board of Vocational Nursing and Psychiatric Technicians.

(v) The Landscape Architects Technical Committee.

(w) The Bureau of Electronic and Appliance Repair.

(x) The Division of Investigation.

(y) The Bureau of Automotive Repair.

(z) The State Board of Registration for Geologists and Geophysicists.

(aa) The Respiratory Care Board of California.
(ab) The Acupuncture Board.
(ac) The Board of Psychology.
(ad) The California Board of Podiatric Medicine.
(ae) The Physical Therapy Board of California.
(af) The Arbitration Review Program.
(ag) The Committee on Dental Auxiliaries.
(ah) The Hearing Aid Dispensers Bureau.
(ai) The Physician Assistant Committee.
(aj) The Speech-Language Pathology and Audiology Board.
(ak) The California Board of Occupational Therapy.
(a*l*) The Osteopathic Medical Board of California.
(am) The Bureau of Naturopathic Medicine.
(an) Any other boards, offices, or officers subject to its jurisdiction by law.

SEC. 2. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks. Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.

(b) Subdivision (a) applies to the following boards, bureaus, or committees:
(1) California Board of Accountancy.
(2) State Athletic Commission.
(3) Board of Behavioral Sciences.
(4) Court Reporters Board of California.
(5) State Board of Guide Dogs for the Blind.
(6) California State Board of Pharmacy.
(7) Board of Registered Nursing.
(8) Veterinary Medical Board.
(9) Registered Veterinary Technician Committee.
(10) Board of Vocational Nursing and Psychiatric Technicians.
(11) Respiratory Care Board of California.
(12) Hearing Aid Dispensers Advisory Commission.
(13) Physical Therapy Board of California.
(14) Physician Assistant Committee of the Medical Board of California.
(15) Speech-Language Pathology and Audiology Board.
(16) Medical Board of California.

(17) State Board of Optometry.
(18) Acupuncture Board.
(19) Cemetery and Funeral Bureau.
(20) Bureau of Security and Investigative Services.
(21) Division of Investigation.
(22) Board of Psychology.
(23) The California Board of Occupational Therapy.
(24) Structural Pest Control Board.
(25) Contractors' State License Board.
(26) The Bureau of Naturopathic Medicine.

SEC. 3. Section 146 of the Business and Professions Code is amended to read:

146. (a) Notwithstanding any other provision of law, a violation of any code section listed in subdivision (c) or (d) is an infraction subject to the procedures described in Sections 19.6 and 19.7 of the Penal Code when:

(1) A complaint or a written notice to appear in court pursuant to Chapter 5c (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code is filed in court charging the offense as an infraction unless the defendant, at the time he or she is arraigned, after being advised of his or her rights, elects to have the case proceed as a misdemeanor, or

(2) The court, with the consent of the defendant and the prosecution, determines that the offense is an infraction in which event the case shall proceed as if the defendant has been arraigned on an infraction complaint.

(b) Subdivision (a) does not apply to a violation of the code sections listed in subdivisions (c) and (d) if the defendant has had his or her license, registration, or certificate previously revoked or suspended.

(c) The following sections require registration, licensure, certification, or other authorization in order to engage in certain businesses or professions regulated by this code:

(1) Sections 2052 and 2054.
(2) Section 2630.
(3) Section 2903.
(4) Section 3660.
(5) Sections 3760 and 3761.
(6) Section 4080.
(7) Section 4825.
(8) Section 4935.
(9) Section 4980.
(10) Section 4996.
(11) Section 5536.
(12) Section 6704.

(13) Section 6980.10.
(14) Section 7317.
(15) Section 7502 or 7592.
(16) Section 7520.
(17) Section 7617 or 7641.
(18) Subdivision (a) of Section 7872.
(19) Section 8016.
(20) Section 8505.
(21) Section 8725.
(22) Section 9681.
(23) Section 9840.
(24) Subdivision (c) of Section 9891.24.
(25) Section 19049.

(d) Institutions that are required to register with the Bureau for Private Postsecondary and Vocational Education pursuant to Section 94931 of the Education Code.

(e) Notwithstanding any other provision of law, a violation of any of the sections listed in subdivision (c) or (d), which is an infraction, is punishable by a fine of not less than two hundred fifty dollars ($250) and not more than one thousand dollars ($1,000). No portion of the minimum fine may be suspended by the court unless as a condition of that suspension the defendant is required to submit proof of a current valid license, registration, or certificate for the profession or vocation which was the basis for his or her conviction.

SEC. 4. Section 149 of the Business and Professions Code is amended to read:

149. (a) If, upon investigation, an agency designated in subdivision (e) has probable cause to believe that a person is advertising in a telephone directory with respect to the offering or performance of services, without being properly licensed by or registered with the agency to offer or perform those services, the agency may issue a citation under Section 148 containing an order of correction that requires the violator to do both of the following:

(1) Cease the unlawful advertising.

(2) Notify the telephone company furnishing services to the violator to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(b) This action is stayed if the person to whom a citation is issued under subdivision (a) notifies the agency in writing that he or she intends to contest the citation. The agency shall afford an opportunity for a hearing, as specified in Section 125.9.

(c) If the person to whom a citation and order of correction is issued under subdivision (a) fails to comply with the order of correction after

that order is final, the agency shall inform the Public Utilities Commission of the violation and the Public Utilities Commission shall require the telephone corporation furnishing services to that person to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(d) The good faith compliance by a telephone corporation with an order of the Public Utilities Commission to terminate service issued pursuant to this section shall constitute a complete defense to any civil or criminal action brought against the telephone corporation arising from the termination of service.

(e) Subdivision (a) shall apply to the following boards, bureaus, committees, commissions, or programs:

(1) The Bureau of Barbering and Cosmetology.
(2) The Funeral Directors and Embalmers Program.
(3) The Veterinary Medical Board.
(4) The Hearing Aid Dispensers Advisory Commission.
(5) The Landscape Architects Technical Committee.
(6) The California Board of Podiatric Medicine.
(7) The Respiratory Care Board of California.
(8) The Bureau of Home Furnishings and Thermal Insulation.
(9) The Bureau of Security and Investigative Services.
(10) The Bureau of Electronic and Appliance Repair.
(11) The Bureau of Automotive Repair.
(12) The Tax Preparers Program.
(13) The California Architects Board.
(14) The Speech-Language Pathology and Audiology Board.
(15) The Board for Professional Engineers and Land Surveyors.
(16) The Board of Behavioral Sciences.
(17) The State Board for Geologists and Geophysicists.
(18) The Structural Pest Control Board.
(19) The Acupuncture Board.
(20) The Board of Psychology.
(21) The California Board of Accountancy.
(22) The Bureau of Naturopathic Medicine.

SEC. 5. Chapter 8.2 (commencing with Section 3610) is added to Division 2 of the Business and Professions Code, to read:

CHAPTER 8.2. NATUROPATHIC DOCTORS ACT

Article 1. General Provisions

3610. This chapter may be cited as the Naturopathic Doctors Act.

3612. The Bureau of Naturopathic Medicine is hereby created within the Department of Consumer Affairs.

3613. The following definitions apply for the purposes of this chapter:

(a) ''Bureau'' means the Bureau of Naturopathic Medicine within the Department of Consumer Affairs.

(b) ''Naturopathic childbirth attendance'' means the specialty practice of natural childbirth by a naturopathic doctor that includes the management of normal pregnancy, normal labor and delivery, and the normal postpartum period, including normal newborn care.

(c) ''Naturopathic medicine'' means a distinct and comprehensive system of primary health care practiced by a naturopathic doctor for the diagnosis, treatment, and prevention of human health conditions, injuries, and disease.

(d) ''Naturopathic doctor'' means a person who holds an active license issued pursuant to this chapter.

(e) ''Naturopathy'' means a noninvasive system of health practice that employs natural health modalities, substances, and education to promote health.

(f) ''Prescription drug'' means any drug defined by Section 503(b) of the federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 353) if its label is required to bear the statement ''RX only.''

3615. The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid, that invalidity shall not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application.

Article 2. Administration

3620. The bureau shall enforce and administer the provisions of this chapter.

3622. The bureau shall adopt regulations in order to carry out the purposes of this chapter.

3623. (a) The bureau shall approve a naturopathic medical education program accredited by the Council on Naturopathic Medical Education or an equivalent federally recognized accrediting body for the naturopathic medical profession that has the following minimum requirements:

(1) Admission requirements that include a minimum of three-quarters of the credits required for a bachelor's degree from a regionally accredited or preaccredited college or university or the equivalency, as determined by the council.

(2) Program requirements for its degree or diploma of a minimum of 4,100 total hours in basic and clinical sciences, naturopathic philosophy, naturopathic modalities, and naturopathic medicine. Of the total requisite hours, not less than 2,500 hours shall consist of academic instruction, and not less than 1,200 hours shall consist of supervised clinical training approved by the naturopathic medical school.

(b) A naturopathic medical education program in the United States shall offer graduate-level full-time studies and training leading to the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine. The program shall be an institution, or part of an institution of, higher education that is either accredited or is a candidate for accreditation by a regional institutional accrediting agency recognized by the United States Secretary of Education and the Council on Naturopathic Medical Education, or an equivalent federally recognized accrediting body for naturopathic doctor education.

(c) To qualify as an approved naturopathic medical school, a naturopathic medical program located in Canada or the United States shall offer a full-time, doctoral-level, naturopathic medical education program with its graduates being eligible to apply to the bureau for licensure and to the North American Board of Naturopathic Examiners that administers the naturopathic licensing examination.

3624. (a) The bureau may grant a certificate of registration to practice naturopathic medicine to a person who does not hold a naturopathic doctor's license under this chapter and is offered a faculty position by the dean of a naturopathic medical education program approved by the bureau, if all of the following requirements are met to the satisfaction of the bureau:

(1) The applicant furnishes documentary evidence that he or she is a United States citizen or is legally admitted to the United States.

(2) The applicant submits an application on a form prescribed by the bureau.

(3) The dean of the naturopathic medical education program demonstrates that the applicant has the requisite qualifications to assume the position to which he or she is to be appointed.

(4) The dean of the naturopathic medical education program certifies in writing to the bureau that the applicant will be under his or her direction and will not be permitted to practice naturopathic medicine unless incident to and a necessary part of the applicant's duties as approved by the bureau.

(b) The holder of a certificate of registration issued under this section shall not receive compensation for or practice naturopathic medicine unless it is incidental to and a necessary part of the applicant's duties in connection with the holder's faculty position.

(c) A certificate of registration issued under this section is valid for two years.

3624.5. (a) This chapter does not apply to a practitioner licensed as a naturopathic doctor in another state or country who meets both of the following requirements:

(1) The practitioner is in consultation with a licensed practitioner of this state, or is an invited guest of any of the following for the purpose of professional education through lectures, clinics, or demonstrations:

(A) The California Medical Association.

(B) The California Podiatric Medical Association.

(C) The California Association of Naturopathic Physicians.

(D) A component county society of subparagraph (A), (B), or (C).

(2) The practitioner does not open an office, appoint a place to meet patients, receive calls from patients, give orders, or have ultimate authority over the care or primary diagnosis of a patient.

3625. (a) The Director of Consumer Affairs shall establish an advisory council consisting of nine members. Members of the advisory council shall include three members who are California licensed naturopathic doctors, or have met the requirements for licensure pursuant to this chapter, three members who are California licensed physicians and surgeons, and three public members.

(b) A member of the advisory council shall be appointed for a four-year term. A person shall not serve as a member of the council for more than two consecutive terms. A member shall hold office until the appointment and qualification of his or her successor, or until one year from the expiration of the term for which the member was appointed, whichever first occurs. Vacancies shall be filled by appointment for unexpired terms. The first terms of the members first appointed shall be as follows:

(1) The Governor shall appoint one physician and surgeon member, one naturopathic doctor member, and one public member, with term expirations of June 1, 2006; one physician and surgeon member with a term expiration date of June 1, 2007, one naturopathic doctor member with a term expiration date of June 1, 2008.

(2) The Senate Rules Committee shall appoint one physician and surgeon member with a term expiration of June 1, 2008, and one public member with a term expiration of June 1, 2007.

(3) The Speaker of the Assembly shall appoint one naturopathic doctor member with a term expiration of June 1, 2007, and one public member with a term expiration of June 1, 2008.

(c) (1) A public member of the advisory council shall be a citizen of this state for at least five years preceding his or her appointment.

(2) A person shall not be appointed as a public member if the person or the person's immediate family in any manner owns an interest in a college, school, or institution engaged in naturopathic education, or the person or the person's immediate family has an economic interest in naturopathy or has any other conflict of interest. ''Immediate family'' means the public member's spouse, parents, children, or his or her children's spouses.

(d) In order to operate in as cost-effective a manner as possible, the advisory council and any advisory committee created pursuant to this chapter shall meet as few times as necessary to perform its duties, and its members shall receive no compensation, travel allowances, or reimbursement for their expenses.

3626. The Director of Consumer Affairs may employ a bureau chief and other officers and employees as necessary to discharge the duties of the bureau.

3627. (a) The bureau shall establish a naturopathic formulary advisory committee to determine a naturopathic formulary based upon a review of naturopathic medical education and training.

(b) The naturopathic formulary advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, pharmacists, and naturopathic doctors.

(c) The naturopathic formulary advisory committee shall review naturopathic education, training, and practice and make specific recommendations regarding the prescribing, ordering, and furnishing authority of a naturopathic doctor and the required supervision and protocols for those functions.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2006, regarding the prescribing and furnishing authority of a naturopathic doctor and the required supervision and protocols, including those for the utilization of intravenous and ocular routes of prescription drug administration. The naturopathic formulary advisory committee and the bureau shall consult with physicians and surgeons, pharmacists, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

3628. (a) The bureau shall establish a naturopathic childbirth attendance advisory committee to issue recommendations concerning the practice of naturopathic childbirth attendance based upon a review of naturopathic medical education and training.

(b) The naturopathic childbirth attendance advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, midwives, and naturopathic doctors.

(c) The naturopathic childbirth attendance advisory committee shall review naturopathic education, training, and practice and make specific recommendations to the Legislature regarding the practice of naturopathic childbirth attendance.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2006. The naturopathic childbirth attendance advisory committee and the bureau shall consult with physicians and surgeons, midwives, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

Article 3. Licensure

3630. An applicant for a license as a naturopathic doctor shall file with the bureau a written application on a form provided by the bureau, that shows, to the bureau's satisfaction, compliance with all of the following requirements:

(a) The applicant has not committed an act or crime that constitutes grounds for denial of a license under Section 480, and has complied with the requirements of Section 144.

(b) The applicant has received a degree in naturopathic medicine from an approved naturopathic medical school where the degree substantially meets the educational requirements in paragraph (2) of subdivision (a) of Section 3623.

3631. An applicant for licensure shall pass the Naturopathic Physicians Licensing Examination (NPLEX) or an equivalent approved by the North American Board of Naturopathic Examiners. In the absence of an examination approved by the North American Board of Naturopathic Examiners, the bureau may administer a substantially equivalent examination.

3633. The bureau may grant a license to an applicant who is licensed and in good standing as a naturopathic doctor in another state, jurisdiction, or territory in the United States, provided the applicant has met the requirements of Sections 3630 and 3631.

3633.1. The bureau may grant a license to an applicant who meets the requirements of Section 3630, but who graduated prior to 1986, pre-NPLEX, and passed a state naturopathic licensing examination. Applications under this section shall be received no later than December 31, 2007.

3634. (a) A license issued under this chapter shall be subject to renewal biennially as prescribed by the bureau and shall expire unless renewed in that manner. The bureau may provide by regulation for the late renewal of a license.

(b) The holder of a license under this chapter shall be required to take and pass a recertifying examination before the 10th anniversary of his or her initial licensure pursuant to this chapter. On or before July 1, 2010, the bureau shall establish standards for recertification and shall create a recertifying examination or adopt an existing examination that satisfies the recertification standards established by the bureau. In developing standards for recertification, the bureau shall consider information provided by the Council on Naturopathic Medical Education, naturopathic doctors, and other interested parties.

3635. (a) In addition to any other qualifications and requirements for licensure renewal, the bureau shall require the satisfactory completion of 60 hours of approved continuing education biennially. This requirement is waived for the initial license renewal. The continuing education shall meet the following requirements:

(1) At least 20 hours shall be in pharmacotherapeutics.

(2) No more than 15 hours may be in naturopathic medical journals or osteopathic or allopathic medical journals, or audio or videotaped presentations, slides, programmed instruction, or computer-assisted instruction or preceptorships.

(3) No more than 20 hours may be in any single topic.

(4) No more than 15 hours of the continuing education requirements for the specialty certificate in naturopathic childbirth attendance shall apply to the 60 hours of continuing education requirement.

(b) The continuing education requirements of this section may be met through continuing education courses approved by the California Association of Naturopathic Physicians, the American Association of Naturopathic Physicians, the Medical Board of California, the California State Board of Pharmacy, the State Board of Chiropractic Examiners, or other courses approved by the bureau.

3636. (a) Upon a written request, the bureau may grant inactive status to a naturopathic doctor who is in good standing and who meets the requirements of Section 462.

(b) A person whose license is in inactive status may not engage in any activity for which a license is required under this chapter.

(c) A person whose license is in inactive status shall be exempt from continuing education requirements while his or her license is in that status.

(d) To restore a license to active status, a person whose license is in inactive status must fulfill continuing education requirements for the two-year period prior to reactivation, and pay a reactivation fee established by the bureau.

3637. Only an individual may be licensed under this chapter.

Article 4. Application of Chapter

3640. (a) A naturopathic doctor may order and perform physical and laboratory examinations for diagnostic purposes, including, but not limited to, phlebotomy, clinical laboratory tests, speculum examinations, orificial examinations, and physiological function tests.

(b) A naturopathic doctor may order diagnostic imaging studies, including X-ray, ultrasound, mammogram, bone densitometry, and others, consistent with naturopathic training as determined by the bureau, but shall refer the studies to an appropriately licensed health care professional to conduct the study and interpret the results.

(c) A naturopathic doctor may dispense, administer, order, and prescribe or perform the following:

(1) Food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act.

(2) Hot or cold hydrotherapy; naturopathic physical medicine inclusive of the manual use of massage, stretching, resistance, or joint play examination but exclusive of small amplitude movement at or beyond the end range of normal joint motion; electromagnetic energy; colon hydrotherapy; and therapeutic exercise.

(3) Devices, including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment.

(4) Health education and health counseling.

(5) Repair and care incidental to superficial lacerations and abrasions, except suturing.

(6) Removal of foreign bodies located in the superficial tissues.

(d) A naturopathic doctor may utilize routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular.

(e) The bureau may establish regulations regarding ocular or intravenous routes of administration that are consistent with the education and training of a naturopathic doctor.

(f) Nothing in this section shall exempt a naturopathic doctor from meeting applicable licensure requirements for the performance of clinical laboratory tests.

(g) The authority to use all routes for furnishing prescription drugs as described in Section 3640.5 shall be consistent with the oversight and supervision requirements of Section 2836.1.

3640.1. The bureau shall make recommendations to the Legislature not later than January 1, 2006, regarding the potential development of scope and supervision requirements of a naturopathic doctor for the

performance of minor office procedures. The bureau shall consult with physicians and surgeons and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

3640.5. Nothing in this chapter or any other provision of law shall be construed to prohibit a naturopathic doctor from furnishing or ordering drugs when all of the following apply:

(a) The drugs are furnished or ordered by a naturopathic doctor in accordance with standardized procedures or protocols developed by the naturopathic doctor and his or her supervising physician and surgeon.

(b) The naturopathic doctor is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the naturopathic doctor, and, where applicable, the facility administrator or his or her designee.

(c) The standardized procedure or protocol covering the furnishing of drugs shall specify which naturopathic doctors may furnish or order drugs, which drugs may be furnished or ordered under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the naturopathic doctor's competence, including peer review, and review of the provisions of the standardized procedure.

(d) The furnishing or ordering of drugs by a naturopathic doctor occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(1) Collaboration on the development of the standardized procedure.

(2) Approval of the standardized procedure.

(3) Availability by telephonic contact at the time of patient examination by the naturopathic doctor.

(e) For purposes of this section, a physician and surgeon shall not supervise more than four naturopathic doctors at one time.

(f) Drugs furnished or ordered by a naturopathic doctor may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the naturopathic doctor and physician and surgeon and specified in the standardized procedure. When Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a naturopathic doctor, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the

naturopathic doctor's standardized procedure relating to controlled substances shall be provided upon request, to a licensed pharmacist who dispenses drugs, when there is uncertainty about the naturopathic doctor furnishing the order.

(g) The bureau has certified in accordance with Section 2836.3 that the naturopathic doctor has satisfactorily completed adequate coursework in pharmacology covering the drugs to be furnished or ordered under this section. The bureau shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term ''furnishing'' in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include both of the following:

(1) Ordering a drug in accordance with the standardized procedure.

(2) Transmitting an order of a supervising physician and surgeon.

(i) For purposes of this section, ''drug order'' or ''order'' means an order for medication which is dispensed to or for an ultimate user, issued by a naturopathic doctor as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations.

(j) Notwithstanding any other provision of law, the following apply:

(1) A drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician.

(2) All references to prescription in this code and the Health and Safety Code shall include drug orders issued by naturopathic doctors.

(3) The signature of a naturopathic doctor on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

3640.7. Notwithstanding the requirements of Section 3640.5 or any other provision of this chapter, a naturopathic doctor may independently prescribe epinephrine to treat anaphylaxis and natural and synthetic hormones.

3641. (a) A naturopathic doctor shall document his or her observations, diagnosis, and summary of treatment in the patient record. Patient records shall be maintained for a period of not less than seven years following the discharge of the patient. The records of an unemancipated minor shall be maintained until at least one year after the minor has reached 18 years of age or seven years following the discharge of the minor, whichever is longer.

(b) A naturopathic doctor shall have the same authority and responsibility as a licensed physician and surgeon with regard to public health laws, including laws governing reportable diseases and conditions, communicable disease control and prevention, recording

vital statistics, and performing health and physical examinations consistent with his or her education and training.

3642. A naturopathic doctor may not perform any of the following functions:

(a) Prescribe, dispense, or administer a controlled substance or device identified in Sections 801 to 971, inclusive, of Title 21 of the United States Code, except as authorized by this chapter.

(b) Administer therapeutic ionizing radiation or radioactive substances.

(c) Practice or claim to practice any other system or method of treatment beyond that authorized by this chapter, for which licensure is required, unless otherwise licensed to do so.

(d) Administer general or spinal anesthesia.

(e) Perform an abortion.

(f) Perform any surgical procedure.

(g) Perform acupuncture or traditional Chinese and oriental medicine, including Chinese herbal medicine, unless licensed as an acupuncturist as defined in subdivision (c) of Section 4927.

3643. This chapter may not be construed to authorize a naturopathic doctor to practice medicine, as defined under Chapter 5 (commencing with Section 2000), except as specifically authorized in this chapter.

3643.5. (a) This chapter may not be construed to limit the practice of a person licensed, certified, or registered under any other provision of law relating to the healing arts when the person is engaged in his or her authorized and licensed practice.

(b) This chapter may not be construed to limit an activity that does not require licensure or is otherwise allowed by law, including the practice of naturopathy, when performed consistent with Sections 2053.5 and 2053.6.

3644. This chapter does not prevent or restrict the practice, services, or activities of any of the following:

(a) A person licensed, certified, or otherwise recognized in this state by any other law or regulation if that person is engaged in the profession or occupation for which he or she is licensed, certified, or otherwise recognized.

(b) A person employed by the federal government in the practice of naturopathic medicine while the person is engaged in the performance of duties prescribed by laws and regulations of the United States.

(c) A person rendering aid to a family member or in an emergency, if no fee or other consideration for the service is charged, received, expected, or contemplated.

(d) A person who makes recommendations regarding or is engaged in the sale of food, extracts of food, nutraceuticals, vitamins, amino

acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, dietary supplements, and nonprescription drugs or other products of nature, the sale of which is not otherwise prohibited under state or federal law.

(e) A person engaged in good faith in the practice of the religious tenets of any church or religious belief without using prescription drugs.

(f) A person acting in good faith for religious reasons as a matter of conscience or based on a personal belief, while obtaining or providing information regarding health care and the use of any product described in subdivision (d).

(g) A person who provides the following recommendations regarding the human body and its function:

(1) Nonprescription products.

(2) Natural elements such as air, heat, water, and light.

(3) Class I or class II nonprescription, approved medical devices, as defined in Section 360c of Title 21 of the United States Code.

(4) Vitamins, minerals, herbs, homeopathics, natural food products and their extracts, and nutritional supplements.

(h) A person who is licensed in another state, territory, or the District of Columbia to practice naturopathic medicine if the person is incidentally called into this state for consultation with a naturopathic doctor.

(i) A student enrolled in an approved naturopathic medical program whose services are performed pursuant to a course of instruction under the supervision of a naturopathic doctor.

3645. (a) This chapter permits, and does not restrict the use of, the following titles by persons who are educated and trained as any of the following:

(1) ‘‘Naturopath.’’

(2) ‘‘Naturopathic practitioner.’’

(3) ‘‘Traditional naturopathic practitioner.’’

(b) This chapter permits, and does not restrict, the education of persons as described in paragraphs (1) to (3), inclusive, of subdivision (a). Those persons are not required to be licensed under this chapter.

Article 5. Naturopathic Childbirth Attendance

3650. A naturopathic doctor may perform naturopathic childbirth attendance if he or she has completed additional training and has been granted a certificate of specialty practice by the bureau.

3651. In order to be certified for the specialty practice of naturopathic childbirth attendance, a naturopathic doctor shall obtain a passing grade on the American College of Nurse Midwives Written

Examination, or a substantially equivalent examination approved by the bureau, and shall establish, to the bureau's satisfaction, compliance with one of the following requirements:

(a) Successful completion of a certificate of midwifery or naturopathic obstetrics specialty from an approved naturopathic medical education program consisting of not less than 84 semester units or 126 quarter units that substantially complies with the following educational standards and requirements:

(1) The curriculum is presented in semester or quarter units under the following formula:

(A) One hour of instruction in the theory each week throughout a semester or quarter equals one unit.

(B) Three hours of clinical practice each week throughout a semester or quarter equals one unit.

(2) The program provides both academic and clinical preparation that is substantially equivalent to that provided in a program accredited by the American College of Nurse Midwives. The program includes, but is not limited to, preparation in all of the following areas:

(A) The art and science of midwifery, one-half of which shall be in theory and one-half of which shall be in clinical practice. Theory and clinical practice shall be concurrent in the areas of maternal and child health, including, but not limited to, labor and delivery, neonatal well care, and postpartum care.

(B) Communications skills that include the principles of oral, written, and group communications.

(C) Anatomy and physiology, genetics, obstetrics and gynecology, embryology and fetal development, neonatology, applied microbiology, chemistry, child growth and development, pharmacology, nutrition, laboratory diagnostic tests and procedures, and physical assessment.

(D) Concepts in psychosocial, emotional, and cultural aspects of maternal and child care, human sexuality, counseling and teaching, maternal and infant and family bonding process, breast feeding, family planning, principles of preventive health, and community health.

(E) Aspects of the normal pregnancy, labor and delivery, postpartum period, newborn care, family planning, or routine gynecological care in alternative birth centers, homes, and hospitals.

(3) The program integrates the following subjects throughout its entire curriculum:

(A) Midwifery process.

(B) Basic intervention skills in preventive, remedial, and supportive midwifery.

(C) The knowledge and skills required to develop collegial relationships with health care providers from other disciplines.

(D) Related behavioral and social sciences with emphasis on societal and cultural patterns, human development, and behavior related to maternal and child health, illness, and wellness.

(4) Instruction in personal hygiene, client abuse, cultural diversity, and the legal, social, and ethical aspects of midwifery.

(5) Instruction in the midwifery management process which shall include all of the following:

(A) Obtaining or updating a defined and relevant database for assessment of the health status of the client.

(B) Identifying problems based upon correct interpretation of the database.

(C) Preparing a defined needs or problem list, or both, with corroboration from the client.

(D) Consulting, collaborating with, and referring to, appropriate members of the health care team.

(E) Providing information to enable clients to make appropriate decisions and to assume appropriate responsibility for their own health.

(F) Assuming direct responsibility for the development of comprehensive, supportive care for the client and with the client.

(G) Assuming direct responsibility for implementing the plan of care.

(H) Initiating appropriate measures for obstetrical and neonatal emergencies.

(I) Evaluating, with corroboration from the client, the achievement of health care goals and modifying the plan of care appropriately, or

(b) Successful completion of an educational program that the bureau has determined satisfies the criteria of subdivision (a) and current licensure as a midwife by a state with licensing standards that have been found by the bureau to be substantially equivalent to those adopted by the bureau pursuant to this article.

3651.5. A naturopathic doctor certified for the specialty practice of naturopathic childbirth attendance shall do both of the following:

(a) Maintain current certification in neonatal resuscitation and cardiopulmonary resuscitation.

(b) File with the bureau a written plan for the following:

(1) Consultation with other health care providers.

(2) Supervision by a licensed physician and surgeon who has current practice or training in obstetrics to assist a woman in childbirth so long as progress meets criteria accepted as normal. The plan shall provide that all complications shall be referred to a physician and surgeon immediately.

(3) Emergency transfer and transport of an infant or a maternity patient, or both, to an appropriate health care facility, and access to

neonatal intensive care units and obstetrical units or other patient care areas.

3652. (a) A certificate of specialty practice in naturopathic childbirth attendance shall expire concurrently with the licensee's naturopathic doctor's license.

(b) The certificate may be renewed upon submission of the renewal fee set by the bureau and evidence, to the bureau's satisfaction, of the completion of 30 hours of continuing education credits in naturopathic childbirth, midwifery, or obstetrics. Fifteen hours may be applied to the 60 hours of continuing education required for naturopathic doctors.

(c) Licensing or disciplinary action by the bureau or a judicial authority shall be deemed to have an equal effect upon the specialty certificate to practice naturopathic childbirth issued to a licensee, unless otherwise specified in the licensing or disciplinary action. When the subject of a licensing or disciplinary action relates specifically to the practice of naturopathic childbirth by a licensee holding a specialty certificate, the action may, instead of affecting the entire scope of the licensee's practice, suspend, revoke, condition, or restrict only the licensee's authority under the specialty certificate.

3653. (a) Naturopathic childbirth attendance does not include the use or performance of any of the following:

(1) Forceps delivery.

(2) General or spinal anesthesia.

(3) Cesarean section delivery.

(4) Episiotomies, except to the extent that they meet the same supervision requirements set forth in Section 2746.52.

(b) Naturopathic childbirth attendance does not mean the management of complications in pregnancy, labor, delivery, or the neonatal period. All complications shall be referred to an obstetrician or other licensed physician and surgeon as appropriate.

3654. In addition to Section 3640, a naturopathic doctor who holds a specialty certificate in naturopathic childbirth attendance may administer, order, or perform any of the following:

(a) Postpartum antihemorrhagic drugs.

(b) Prophylactic opthalmic antibiotics.

(c) Vitamin K.

(d) RhoGAM.

(e) Local anesthetic medications.

(f) Intravenous fluids limited to lactated ringers, 5 percent dextrose with lactated ringers, and heparin and 0.9 percent sodium chloride for use in intravenous locks.

(g) Epinephrine for use in maternal anaphylaxis pending emergency transport.

(h) Measles, mumps, and rubella (MMR) vaccine to nonimmune, nonpregnant women.

(i) HBIG and GBV for neonates born to hepatitis B mothers, per current Centers for Disease Control guidelines.

(j) Antibiotics for intrapartum prophylaxis of Group B Betahemolytic Streptococcus (GBBS), per current Centers For Disease Control guidelines.

(k) Equipment incidental to the practice of naturopathic childbirth, specifically, dopplers, syringes, needles, phlebotomy equipment, suture, urinary catheters, intravenous equipment, amnihooks, airway suction devices, neonatal and adult resuscitation equipment, glucometer, and centrifuge.

(*l*) Equipment incidental to maternal care, specifically, compression stockings, maternity belts, breast pumps, diaphragms, and cervical caps.

3655. (a) A licensee holding a speciality certificate in naturopathic childbirth attendance shall disclose to each client, in writing, the following:

(1) The qualifications and credentials of the naturopathic doctor.

(2) A copy of the written plan for consultation, emergency transfer, and transport.

(3) A description of the procedures, benefits, and risks of birth in the home or outside of a hospital setting.

(4) The status of liability coverage of the licensee for the practice of naturopathic childbirth attendance.

(b) The form must be signed by the client, filed in the client's chart, and a copy given to the client.

Article 6. Offenses and Enforcement

3660. Except as provided in subdivision (h) of Section 3644, a person shall have a valid, unrevoked, or unsuspended license issued under this chapter to do any of the following:

(a) To claim to be a naturopathic doctor, licensed naturopathic doctor, doctor of naturopathic medicine, doctor of naturopathy, or naturopathic medical doctor.

(b) To use the professional abbreviation ''N.D.'' or other titles, words, letters, or symbols with the intent to represent that he or she practices, is authorized to practice, or is able to practice naturopathic medicine as a naturopathic doctor.

3661. A naturopathic doctor who uses the term or designation ''Dr.'' shall further identify himself or herself as ''Naturopathic Doctor,'' ''Licensed Naturopathic Doctor,'' ''Doctor of Naturopathic Medicine,'' or ''Doctor of Naturopathy'' and shall not use any term or designation

that would tend to indicate the practice of medicine, other than naturopathic medicine, unless otherwise licensed as a physician and surgeon, osteopathic doctor, or doctor of chiropractic.

3662. It shall constitute unprofessional conduct for a naturopathic doctor to violate, attempt to violate, assist in the violation of, or conspire to violate, any provision or term of this chapter or any regulation adopted under it.

3663. The bureau may discipline a naturopathic doctor for unprofessional conduct. After a hearing conducted in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), the bureau may deny, suspend, revoke, or place on probation the license of, or reprimand, censure, or otherwise discipline a naturopathic doctor in accordance with Division 1.5 (commencing with Section 475).

3664. A person who violates Section 3660 or 3661 is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not more than five thousand dollars ($5,000), or by imprisonment of not more than one year in a county jail, or by both that fine and imprisonment.

Article 7. Naturopathic Corporations

3670. A naturopathic corporation is a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, if the corporation and its shareholders, officers, directors, and employees rendering professional services who are naturopathic doctors are in compliance with the Moscone-Knox Professional Corporation Act (Part 4 (commencing with Section 13400) of Division 3 of Title 1 of the Corporations Code), this chapter, and all other statutes and regulations now or hereafter enacted or adopted pertaining to that corporation and the conduct of its affairs. With respect to a naturopathic corporation, the governmental agency referred to in the Moscone-Knox Professional Corporation Act is the bureau.

3671. A naturopathic corporation shall not engage in any conduct that constitutes unprofessional conduct. In the conduct of its practice, the naturopathic corporation shall comply with statutes and regulations to the same extent as an individual holding a license under this chapter.

3672. The income of a naturopathic corporation attributable to professional services rendered while a shareholder is a disqualified person, as defined in Section 13401 of the Corporations Code, shall not in any manner accrue to the benefit of the shareholder or his or her shares in the naturopathic corporation.

3673. Except as provided in Section 13403 of the Corporations Code, each director, shareholder, and officer of a naturopathic corporation, except an assistant secretary and an assistant treasurer, shall be a licensed person as defined by Section 13401 of the Corporations Code.

3674. The name of a naturopathic corporation and any name or names under which it may render professional services, shall contain the words ''naturopathic'' or ''naturopathic doctor'' and, as appropriate, wording or abbreviations denoting its status as a corporation.

3675. The bureau may adopt and enforce regulations to carry out the purposes and objectives of this article, including, but not limited to, regulations requiring the following:

(a) That the bylaws of a naturopathic corporation include a provision whereby the capital stock of the corporation owned by a disqualified person, as defined in Section 13401 of the Corporations Code, or a deceased person, shall be sold to the corporation or to the remaining shareholders of the corporation within any time as the regulations may provide.

(b) That a naturopathic corporation shall provide adequate security by insurance or otherwise for claims against it by its patients arising out of the rendering of professional services.

Article 8. Fiscal Administration

3680. The bureau shall establish the amount of the fee assessed to conduct activities of the bureau, including the amount of fees for applicant licensure, licensure examination, licensure renewal, late renewal, and childbirth certification.

3681. (a) All fees collected by the bureau shall be paid into the State Treasury and shall be credited to the Naturopathic Doctor's Fund which is hereby created in the State Treasury. The money in the fund shall be available to the bureau for expenditure for the purposes of this chapter only upon appropriation by the Legislature.

(b) Notwithstanding subdivision (a), all money other than revenue described in Section 207 received and credited to the Naturopathic Doctor's Fund in the 2003–04 fiscal year is hereby appropriated to the bureau for the purpose of implementing this chapter.

Article 9. Miscellaneous Provisions

3685. (a) The provisions of Article 8 (commencing with Section 3680) shall become operative on January 1, 2004, but the remaining provisions of this chapter shall become operative on July 1, 2004. It is

the intent of the Legislature that the initial implementation of this chapter be administered by fees collected in advance from applicants. Therefore, the bureau shall have the power and authority to establish fees and receive applications for licensure or intents to file application statements on and after January 1, 2004. The department shall certify that sufficient funds are available prior to implementing this chapter. Funds from the General Fund may not be used for the purpose of implementing this chapter.

(b) This chapter shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute that is enacted before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this chapter renders the bureau subject to the review required by Division 1.2 (commencing with Section 473).

(c) The bureau shall prepare the report required by Section 473.2 no later than September 1, 2007.

SEC. 6. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation:

(a) Medical corporation.

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(b) Podiatric medical corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(c) Psychological corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(g) Marriage and family therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.

(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.

(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage, family, and child counselors.
(10) Licensed clinical social workers.
(11) Licensed optometrists.

SEC. 7. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation:

(a) Medical corporation.
(1) Licensed doctors of podiatric medicine.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(b) Podiatric medical corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(c) Psychological corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.

(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(g) Marriage and family therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.

(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage, family, and child counselors.
(10) Licensed clinical social workers.
(11) Licensed optometrists.
(n) Dental corporation.
(1) Licensed physician and surgeons.
(2) Dental assistants.
(3) Registered dental assistants.
(4) Registered dental assistants in extended functions.
(5) Registered dental hygienists.

(6) Registered dental hygienists in extended functions.

(7) Registered dental hygienists in alternative practice.

SEC. 8. Section 7 of this bill incorporates amendments to Section 13401.5 of the Corporations Code proposed by both this bill and AB 123. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends Section 13401.5 of the Corporations Code, and (3) this bill is enacted after AB 123, in which case Section 6 of this bill shall not become operative.

SEC 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment H

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Legislation and Regulation Committee
Strategic Plan Update for October 2003

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 3. Sponsor legislation to add enforcement options for non-compliance issues. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. **Advocacy: AB 1196, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774** **Technical Assistance: AB 262, AB 746, AB 1196, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907** 6. Sponsor clean-up language to B & P Code section 4312. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. **Public meetings held on March 27, 2003 and September 11, 2003. Public meeting scheduled for January 8, 2004.**

Objective 3.2:	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.**
Measure:	**Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. **In process. Final board vote scheduled for October 2003.** 2. Authorize the executive officer the authority to issue citations and fines. **Completed. Regulation effective October 11, 2003.** 3. Eliminate the clerk typist ratio. **September 2003 - Informational hearing held. Action deferred.** 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. **September 2003 - Informational hearing held. Action deferred.** 5. Update pharmacy Self-Assessment document. 6. Allow central filling by hospital pharmacies. **September 2003 - Informational hearing held. Awaiting publication of notice.** 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. **September 2003 - Informational hearing held. Awaiting publication of notice.**

Objective 3.3:	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.**
Measure:	**Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. **Completed – Chapter 250, Statutes of 2003 (SB 175)** 3. Evaluate group dispensing by prescribers. **August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.**

Attachment I

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MEETING MINUTES
LEGISLATION AND REGULATION COMMITTEE
DATE: SEPTEMBER 11, 2003
LOCATION: BOARD OF PHARMACY
400 R STREET, SUITE 4070
SACRAMENTO, CA 95814

BOARD MEMBERS PRESENT:

ANDREA ZINDER, CHAIR
DAVE FONG

BOARD STAFF PRESENT:

PATRICIA HARRIS
ROBERT RATCLIFF
VIRGINIA HEROLD
PAUL RICHES

The meeting was convened at 10:35 a.m.

The chair recognized the following board members in attendance Clarence Hiura, Ruth Conroy and James Acevedo.

Legislation Update

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."
Board Position: Support
Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.
Board Position: Support
Status: Senate Rules Committee/Two-year bill

AB 1363 (Berg) Establishes requirements for needle exchange programs.
Board Position: Support
Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy.
Board Position: Support
Status: Two-year bill

SB 151 (Burton) Eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper resistant prescribing pad for all controlled substance prescriptions. Adds Schedule III drugs to CURES.

Board Position: Support
Status: Enrolled to the Governor

SB 175 (Kuehl) Adds veterinary drugs to the definition of dangerous drugs.
Board Position: Support
Status: Signed by the Governor (Chapter 250, Statutes of 2003)

SB 361 (Figueroa) Sunset Review Bill
Board Position: Support
Status: Enrolled to the Governor

SB 393 (Aanestad) Permits "tech check tech" in hospitals.
Board Position: Support if Amended
Status: Two-year bill

SB 490 (Alpert) Establishes a statewide protocol for pharmacists dispensing emergency contraception.
Board Position: Support
Status: Enrolled to the Governor

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.
Board Position: Oppose
Status: Two-year bill

SB 545 (Speier) Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. Eliminates the training requirement for a pharmacist to dispense emergency contraception.
Board Position: Neutral
Status: Enrolled to the Governor

SB 774 (Vasconcellos) Eliminates the prescription requirement for hypodermic needles and syringes.
Board Position: Support
Status: Enrolled to the Governor

Bills of Interest

AB 57 (Bates) Places MDMA into Schedule II.
Status: Assembly Inactive File

AB 186 (Correa) Makes technical changes to the Pharmacy Law relating to optometrists.
Status: Enrolled to the Governor

AB 292 (Yee) Prohibits minors from providing translation services.
Status: Senate Appropriations Committee

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.
Status: Senate Business and Professions Committee

AB 1196 (Montanez) Permits nurse practitioners to order Schedule II drugs.
Status: Enrolled to the Governor

SB 292 (Speier) Requires prescription labels to have a description of the drug.
Status: Enrolled to the Governor

Regulations Update

The committee was provided with an update on the status of pending regulation packages as follows:

Section 1732.2 – Continuing Education
Status: Approved by OAL on August 27, 2003.

Section 1751 – Sterile Compounding
Status: Awaiting final board vote.

Section 1775 – Citation and Fine
Status: Awaiting OAL approval.

Informational Hearings

Section 1710 Hospital Central Fill –

Mr. Steve Gray representing Kaiser Permanente supports the proposed regulation. Mr. Gray requested that the regulation be amended to permit a community pharmacy to provide the central fill function for a hospital pharmacy. The committee supported such an amendment.

Mr. Gray further questioned whether an exempt hospital (less than 100 beds) that could utilized a central fill operation under the proposed regulation. The committee indicated that such a hospital pharmacy could utilize a central fill operation under the proposed regulation.

The committee recommended moving forward with the regulation per the comments provided.

Section 1709.1 Pharmacist-In-Charge –

Ms. Andrea Zinder indicated her continued opposition to the proposed regulation because she believes that it will undermine public safety by overburdening pharmacists-in-charge (PIC).

Mr. Dave Fong indicated that he believes there are pharmacists who can serve effectively as pharmacist-in-charge at two locations and provide sufficient supervision to ensure public

protection. Mr. Fong further indicated that the provisions in the proposed regulation that permit pharmacists to decline to act as a PIC provide additional public protection.

Mr. Fong indicated that the board should do more to promote and define the role of the PIC so that more pharmacists would be willing to take on the role.

Ms. Zinder indicated that the board should move slowly on this proposal until the board can clarify expectations for PICs.

Mr. Steve Gray representing Kaiser Permanente, indicated support for the proposed regulation. Mr. Gray further indicated that the proposal would free many pharmacists from being PIC in pharmacies located in Kaiser medical office buildings. In many cases, there are multiple pharmacies in each building and the PIC in the central pharmacy could serve in that role in the smaller pharmacy thus freeing another staff pharmacist from that duty.

Mr. Shane Gusman representing the United Food and Commercial Workers (UFCW) indicated that UFCW shared many of the concerns expressed by Ms. Zinder. Mr. Gusman indicated that UFCW could not support the proposed regulation without some reasonable geographic restriction and that, while UFCW appreciates the discretion language in the proposed regulation, many pharmacists would not exercise the discretion because pharmacy owners will exert considerable pressure on pharmacists to undertake the additional responsibility.

Mr. Dave Fong indicated that a reasonable geographic restriction would be valuable.

Ms. Michelle Snyder representing SaveMart indicated that allowing an experienced PIC to serve at two locations would provide an opportunity for them to train younger pharmacists to become PIC.

Mr. Carlo Michelotti representing the California Pharmacists Association (CPhA) indicated support for the proposed regulation. However, CPhA would like to see greater specificity including a geographic restriction and a better expression of the board's expectations of the PIC. Mr. Michelotti further indicated that some definition of the minimum adequate time required for the PIC to work at each location.

Mr. Gray indicated a need to preserve the interim PIC rule because it is frequently difficult to identify a replacement PIC on short notice.

The committee recommended that the staff draft a new proposed regulation including a geographic restriction and a time requirement element and bring that draft to the board in October 2003.

Section 1717.1 Common Electronic Files –

Mr. Paul Riches summarized the revised text provided at the meeting that retains the existing common electronic file and public notice requirement and adds a requirement that

pharmacies have written policies and procedures to ensure only authorized individuals have access to confidential patient information.

The committee recommended moving forward with the regulation per the revised text.

Section 1717.4 Authenticity of Prescriptions –

Mr. Steve Gray representing Kaiser Permanente supported the regulation as bringing California law into compliance with the standards recently adopted by the Drug Enforcement Administration regarding prescribing.

The committee recommended moving forward with the proposed regulation.

Section 1793.3 Clerk-Typists –

Ms. Andrea Zinder indicated that the board should withhold action on this regulation because the stakeholders are working on a statutory proposal to revise the existing staffing ratios to a single "global" ratio that would include all ancillary personnel.

Mr. Dave Fong indicated that he was impatient for this important change to occur and that he was not willing to delay such necessary changes indefinitely.

Mr. Shane Gusman representing the UFCW indicated that the stakeholders were close to an agreement on a "global" ratio but that moving forward with this regulation could destroy the emerging consensus on a "global" ratio. Mr. Gusman indicated that increasing clerks to help manage problems with third party payment issues but that increasing the number of clerks needs to be tied to the overall level of staffing in the pharmacy.

Mr. Carlo Michelotti representing the CPhA indicated that his organization has not been party to the discussions on a "global" ratio. Mr. Michelotti indicated that CPhA is okay with the proposal in principal if the pharmacist is actually in control of the pharmacy and not manipulated by the pharmacy owner. Mr. Michelotti further indicated that the existing law that requires shuffling name badges and activities based on arbitrary statutory ratios is bad policy.

The committee recommended holding the regulation until the January board meeting and to solicit comments on a "global" ratio at the October 2003 board meeting.

Technical Regulation Changes

The committee recommended staff develop a Section 100 filing to revise existing board regulations based on the numerous statutory changes in the 2003 legislative session.

Public Suggestions for legislative changes in 2004

Mr. Steve Gray representing Kaiser Permanente requested changes to prescription labeling law that would remove the requirement that a supervising physician's name be included on a prescription label for a prescription issued by another practitioner (nurse practitioner, physician assistant, etc.) working under protocol.

Mr. Gray further suggested that existing law be amended to allow any pharmacist (not just the PIC) be allowed to sign for delivery of dangerous drugs or dangerous devices.

The committee recommended moving forward with both items as omnibus changes for 2004.

Future Meetings.

The committee agreed to conduct its next meeting on January 8, 2004 at 10:30 a.m.

Adjournment

The committee adjourned at 12:10 p.m.